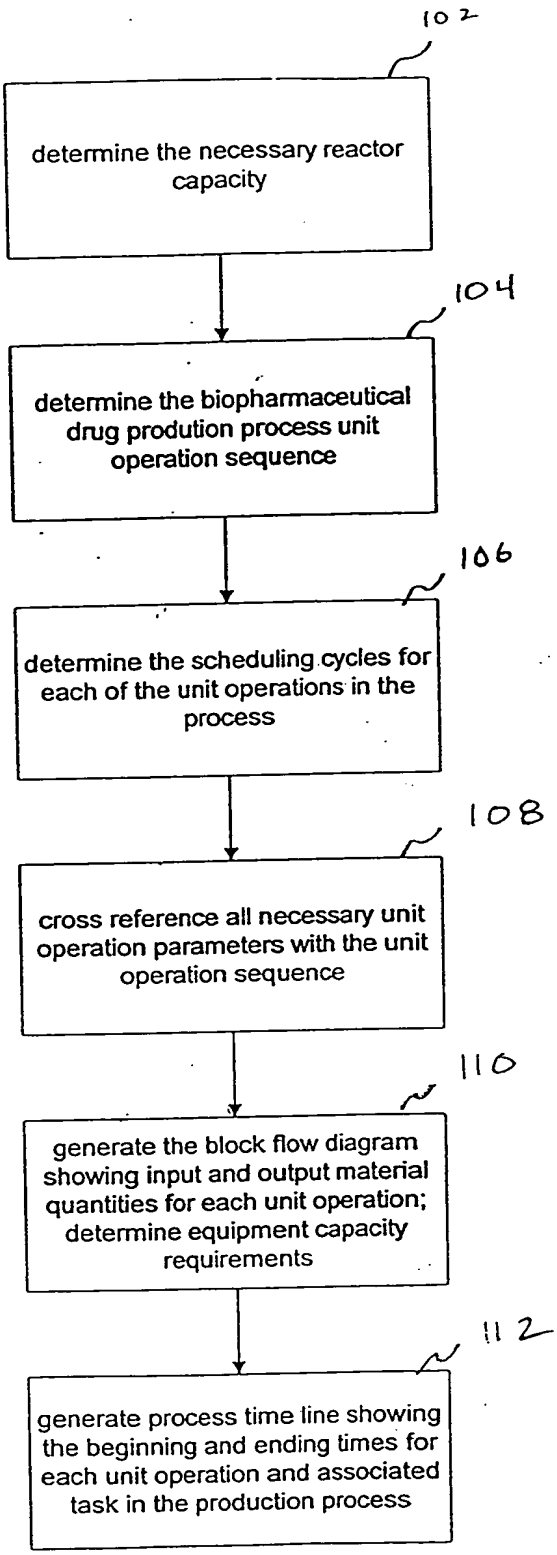

102
determine the necessary reactor capacity
104
determine the biopharmaceutical drug prodution process unit operation sequence
106
determine the scheduling cycles for each of the unit operations in the process
108
cross reference all necessary unit operation parameters with the unit operation sequence
110
generate the block flow diagram showing input and output material quantities for each unit operation; determine equipment capacity requirements
112
generate process time line showing the beginning and ending times for each unit operation and associated task in the production process

FIG. 1

102

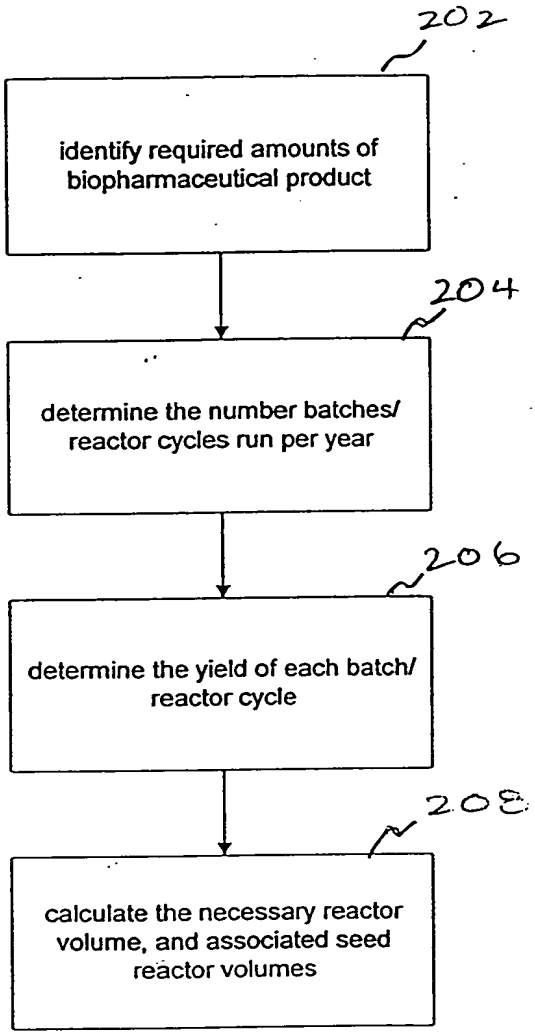

202
identify required amounts of biopharmaceutical product
204
determine the number batches/ reactor cycles run per year
206
determine the yield of each batch/ reactor cycle
208
calculate the necessary reactor volume, and associated seed reactor volumes

FIG. 2

Unit Operations List

Microbial Fermentation Process

UOP Seq. No.	Code	Unit Operation Type	Cycles per UnOp	Offset (Hrs)	Batch UnOp Start	Batch UnOp End	Batch Offset (Hrs)	Process UnOp Start	Process UnOp End	Process Offset (Hrs)	Recovery Product SWR	Recovery Product OAR	Recovery Total Protein SWR	Recovery Total Protein OAR
1	1	Inoculum Prep	1		3	1	6	1						
2	2	Flask Growth	1		3	1	6	1						
3	53	Seed Fermentation	1		3	1	6	1						
4	3	Production Fermentation	1		3	1	6	1			100%	100%	100%	100%
5	51	Heat Exchange	1		3	1	6	1			100%	100%	100%	100%
6	28	Cont. Centrifugation/Whole Cell Harvest	1		3	1	6	1			95%	95%	95%	95%
7	48	Resuspend Cell Paste	1		1			1			100%	95%	100%	95%
8	51	Heat Exchange	1		3	8	10	1			100%	95%	100%	95%
9	31	Cell Disruption/ High Pressure	1		3	8	10	1			80%	76%	90%	86%
10	51	Heat Exchange	1		3	8	10	1			100%	76%	100%	86%
11	48	Resuspension/Surfactant	1		2	11	12	1			100%	76%	95%	81%
12	29	Cont. Centrifugation/Precipitate Harvest	1		2	11	12	1			95%	72%	32%	26%
13	48	Resuspension/Buffer	1		1			1			100%	72%	95%	24%
14	29	Ultrafiltration/Concentration/Dilution	1		1			1			95%	69%	95%	23%
15	48	Microfiltration/Tangential Flow	1		1			1			93%	64%	95%	22%
16	36	Product Adsorption MPLC	1		1			1			85%	54%	33%	7%
17	34	Product Adsorption MPLC	1		1			1			90%	49%	40%	3%
18	39	Ultrafiltration/Flow Dialysis	1		1			1			95%	46%	95%	3%
19	39	Product Adsorption MPLC	1		1			1			85%	39%	55%	2%
20	37	Ultrafiltration/Flow Dialysis	1		1			1			90%	35%	95%	1%
21	39	Product Adsorption MPLC	1		1			1			90%	32%	80%	1%
22	37	Microfiltration/Dead End	1		1			1			95%	30%	95%	1%
23	99	End												

302 304 306 308 310 312 314 316 318 320 322 324 326 328 330 332

FIG. 3

Unit Operations List

Mammalian Cell Culture Process

UOP Seq. No.	Code	Unit Operation Type	Cycles per UnOp		Batch			Process			Recovery			
				Offset (Hrs)	UnOp Start	UnOp End	Offset (Hrs)	UnOp Start	UnOp End	Offset (Hrs)	Product SWR	Product OAR	Total Protein SWR	Total Protein OAR
1	4	Initial Seeding	1		1			1						
2	5	Culture Vessel Split	1		1			1						
3	5	Culture Vessel Split	1		1			1						
4	5	Culture Vessel Split	1		1			1						
5	6	Spinner Flask Split	1		1			1						
6	54	Spinner Flask Split	1		1			1						
7	13	Stirred Tank Reactor	1		1			1						
8	61	Harvest/Feed	7	24	1			8	8	18	168			
9	62	Harvest Pool	1		1			8	8	18	168			
10	34	MF/Tangential Flow	1		1			8	8	18	168			
11	36	UF/Concentration	1		1			8	8	18	168			
12	39	PAC/MPLC	1		1			8	8	18	168			
13	39	PAC/MPLC	1		1			8	8	18	168			
14	36	UF/Concentration	1		1			8	8	18	168			
15	39	PAC/MPLC	1		1			8	8	18	168			
16	37	UF/Flow Dialysis	1		1			8	8	18	168			
17	39	PAC/MPLC	1		1			8	8	18	168			
18	35	MF/Dead End	1		1			8	8	18	168			
19	99	End	1		1			8	8	18	168			

402 404 406 408 410 412 414 416 418 420 422 424

FIG. 4

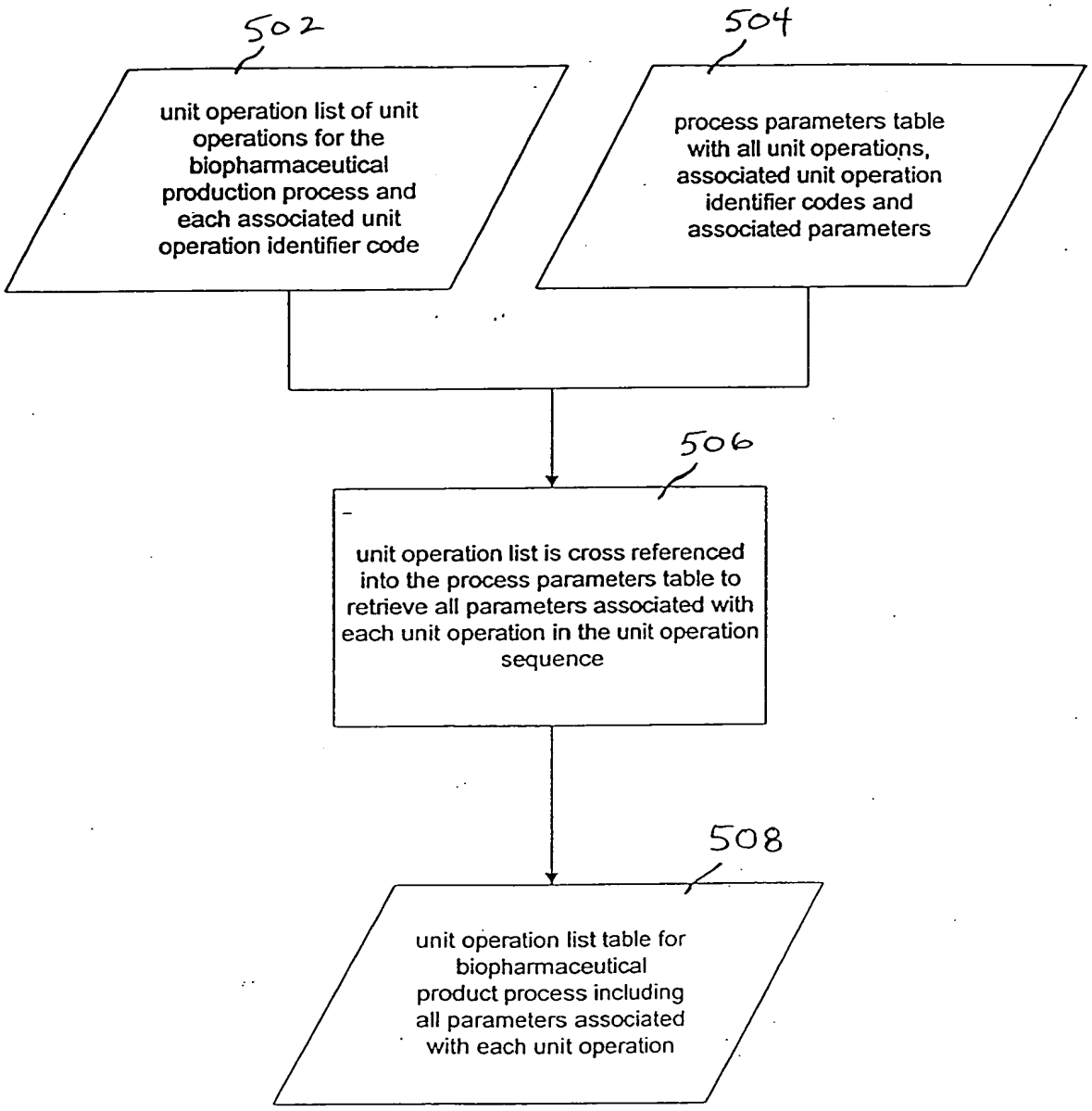

502
unit operation list of unit operations for the biopharmaceutical production process and each associated unit operation identifier code
504
process parameters table with all unit operations, associated unit operation identifier codes and associated parameters
506
unit operation list is cross referenced into the process parameters table to retrieve all parameters associated with each unit operation in the unit operation sequence
508
unit operation list table for biopharmaceutical product process including all parameters associated with each unit operation

FIG. 5

unit operation id code	Unit operation type	Parameters	solution type	tasks	task duration
1	inoculum prep	# of flasks, volume of flasks, termperature, agitation, duration, final OD	S-101	setup, preincubation, incubation, clean up	3, 3, 23, .3 Hrs
2	flask growth	scale up ratio, media volume, termperature, agitation, duration, final OD	S-101	setup, preincubation, incubation, clean up	1, 1, 23, .3 Hrs
3	fermentation seed	scale up ratio, fermentor working volume, antifoam, base acid, grow temperature, agitation, sparge rate, back pressure, total duration	S-101, 102, 103, 104, 105	setup, preincubation, fermentation, harvest, CIP, SIP, clean up	1, 1, 21, .5, 1, 1, 3 Hrs
4	fermentation production	scale up ratio, germentor working volume, antifoam A, antifoam B, base, acid, grow termperature, agitation, sparge rate, back pressure, total duration, final OK, dry cell mass, product concentration, CIP, SIP	S-101, 102, 103, 104, 105	setup preincubation, fermentation, CIP, SIP, cleanup	•
5	heat exchange	process initial & final temp; utility initial & final temp; process specific heat; design type, step recovery of product, step recovery of T.P., termperature regulation, CIP, SIP		setup, transfer, CIP, SIP, cleanup	•
6	batch centrifugation	system void volume, RCF, time, voulume reduction, wash volume, clean, rinse	S-106	setup, centrifugation, wash, CIP, SIP, cleanup	•
7	resolublization resuspension	reagent/product ratio, titration solution, resolubilization, agitation, solution name, step recovery of the product, step recovery of T.P., termperature regulation, CIP, SIP	S-107	setup, dilution, agitate, CIP, SIP, clean up	•
8	Cell Disruption High Press. Hommogenization	product temperature, unlity temperature, void volume, number of passes, pressure, flow rate, termperature increase, wash, rinse, step recovery of product, step recovery of T.P., temperature regulation, CIP	S-107	setup, lysis, CIP, SIP, clean up	•
9	Dilute with Surfactant	reagent product ratio, titration solution, dilution time, agitation, solution name, step recovery of product, step recovery of T.P., termperature regulation, CIP, SIP	S-108	setup, dilution, agitate, CIP, SIP, clean up	•
10	batch centrifugation preciptate harvest	system void volume, RCF, time, volume reduciton, wash volume, clean, rinse, step recovery of product, step recovery of T.P., temperature regulation, CIP, SIP	S-108	setup, centrifugation, wash, CIP, SIP, clean up	•
11	resuspend with chaotrope	reagent/product ratio, titration solution, resolubilization, agitation, solution name, step recovery of product, steop recovery to TP, temperature regulation, CIP, SIP	S-109	setup, flush, prime, concentration, dilution, wahs, flush, store, CIP, SIP, cleanup	•
•	•	•	•	•	•
•	•	•	•	•	
•	•	•	•	•	
•	•	•	•	•	

FIG. 6

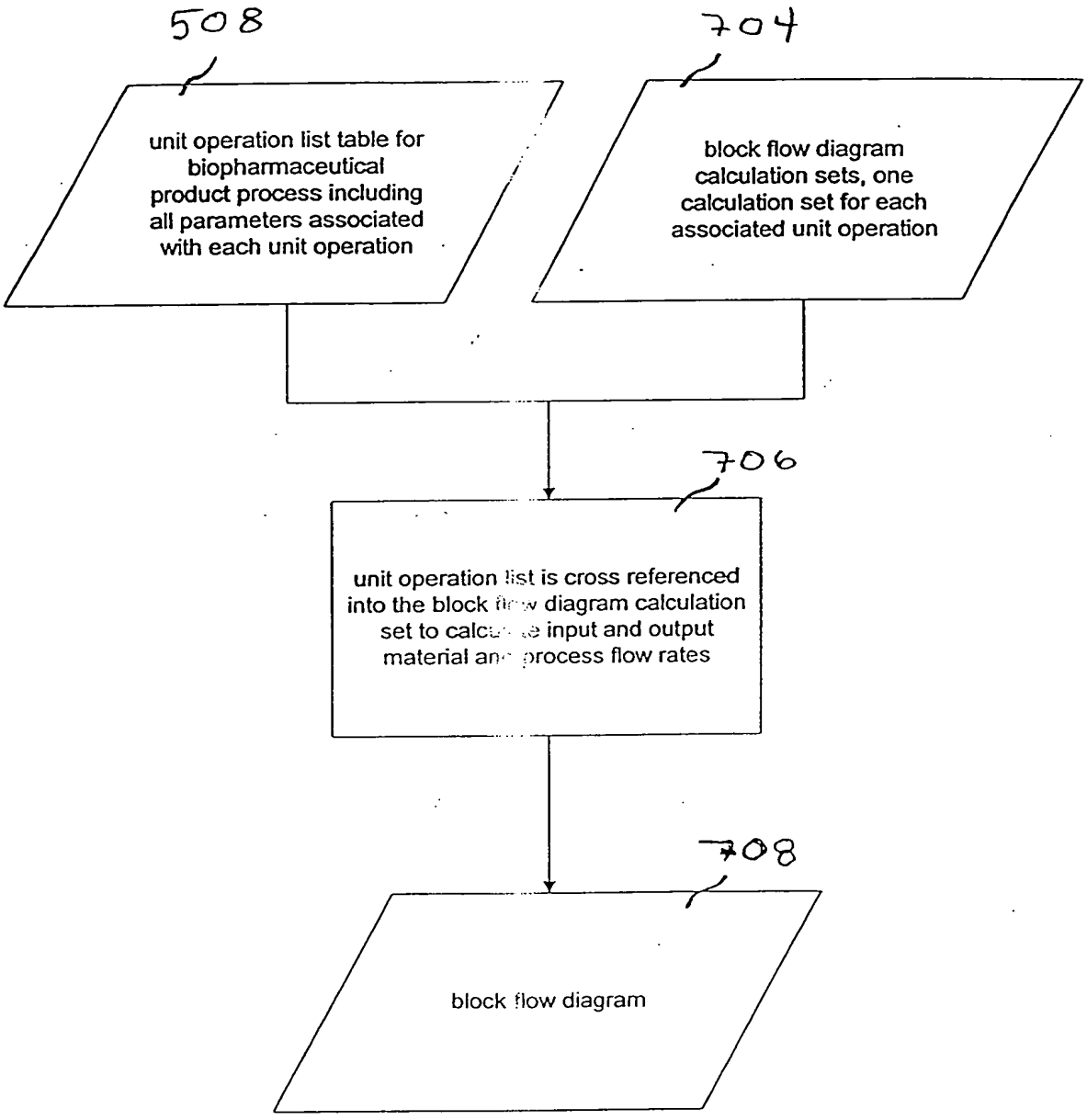

508
704
unit operation list table for biopharmaceutical product process including all parameters associated with each unit operation
block flow diagram calculation sets, one calculation set for each associated unit operation
706
unit operation list is cross referenced into the block flow diagram calculation set to calculate input and output material and process flow rates
708
block flow diagram

FIG. 7

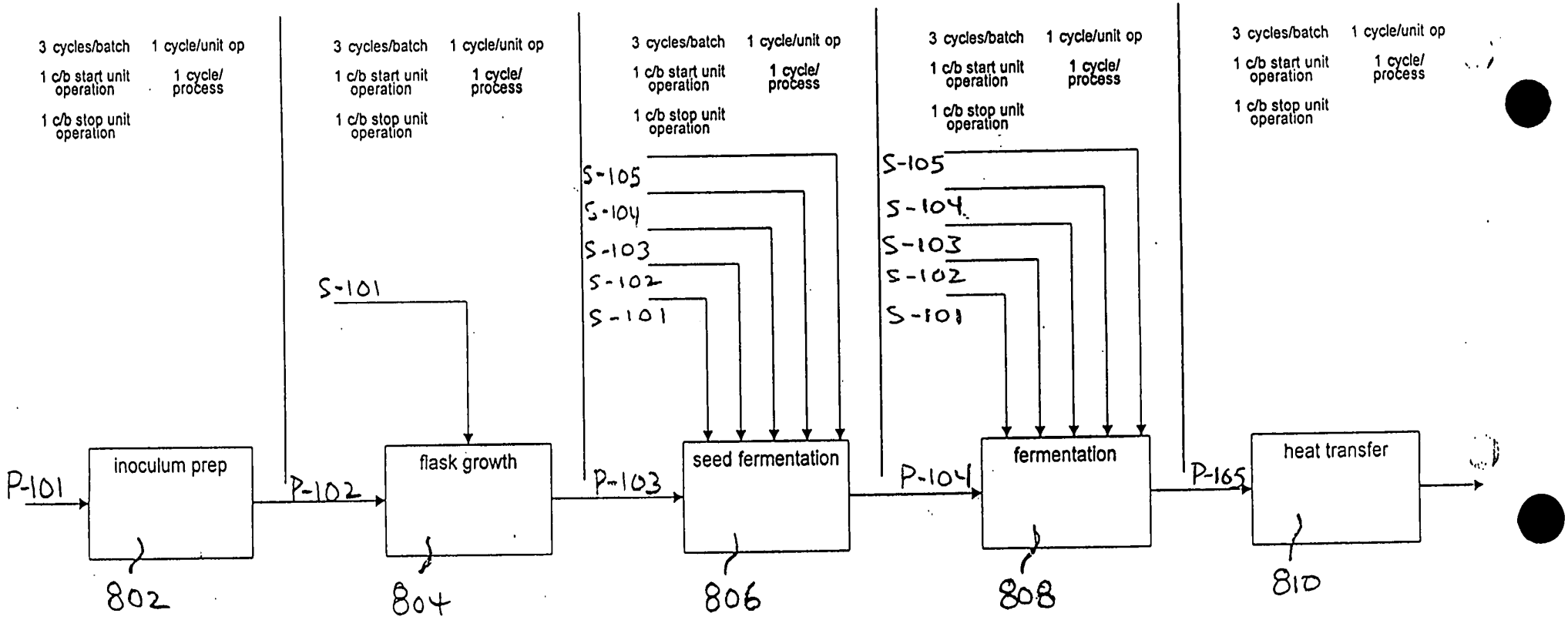

3 cycles/batch
1 c/b start unit operation
1 c/b stop unit operation
1 cycle/unit op
1 cycle/ process
P-101
inoculum prep
802
P-102
S-101
flask growth
804
P-103
S-105
S-104
S-103
S-102
S-101
seed fermentation
806
P-104
fermentation
808
P-165
heat transfer
810

FIG. 8

110

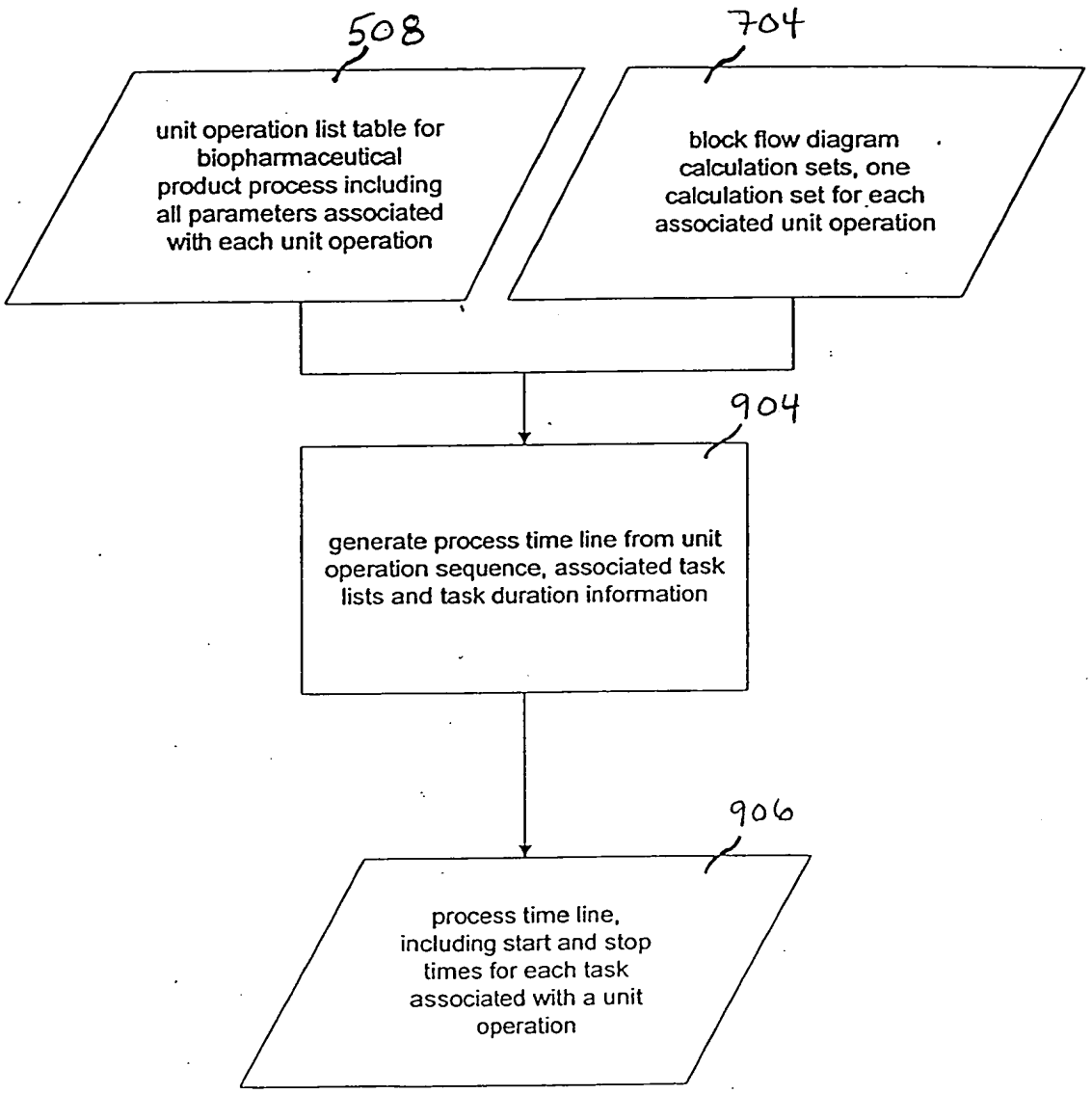

508
unit operation list table for biopharmaceutical product process including all parameters associated with each unit operation
704
block flow diagram calculation sets, one calculation set for each associated unit operation
904
generate process time line from unit operation sequence, associated task lists and task duration information
906
process time line, including start and stop times for each task associated with a unit operation

FIG. 9

Sample Application of Process Design Cycles In Process Scheduling

Microbial Fermentation Process (see unit operation list)

			First Process Cycle		Second Process Cycle	
		Duration	Week	Day	Week	Day

Note: None of the unit operations in this process have more that 1 cycle per unit operation (see unit operation 8 in the mammalian cell culture process for an example of multiple cycles per unit operation)

Unit Operations 1-6 undergo three repetative cycles per batch as a set before continuing with unit op 7
This translates to three runs on a fermentor with each harvest (unit op 5 & 6) being stored for pooling at unit op 7
Associated with each fermentor run (unit op 4) are the previous steps for innoculation prep (unit ops 1-3)

1/3 fermentation cycles per batch						
	1	Inoculum Prep	24 hrs	1	Fri - Sat	2 Fri - Sat
	2	Flask Growth	24 hrs	2	Sat - Sun	3 Sat - Sun
	3	Seed Fermentation	24 hrs	2	Sun - Mon	3 Sun - Mon
	4	Production Fermentation	24 hrs	2	Mon - Tue	3 Mon - Tue
	5	Heat Exchange	1 hr	2	Tue	3 Tue
	6	Centrifugation	1hr	2	Tue	3 Tue
2/3 fermentation cycles per batch						
	1	Inoculum Prep	24 hrs	2	Sun - Mon	3 Sun - Mon
	2	Flask Growth	24 hrs	2	Mon - Tue	3 Mon - Tue
	3	Seed Fermentation	24 hrs	2	Tue - Wed	3 Tue - Wed
	4	Production Fermentation	24 hrs	2	Wed - Thu	3 Wed - Thu
	5	Heat Exchange	1 hr	2	Thu	3 Thu
	6	Centrifugation	1hr	2	Thu	3 Thu
3/3 fermentation cycles per batch						
	1	Inoculum Prep	24 hrs	2	Tue - Wed	3 Tue - Wed
	2	Flask Growth	24 hrs	2	Wed - Thu	3 Wed - Thu
	3	Seed Fermentation	24 hrs	2	Thu - Fri	3 Thu - Fri
	4	Production Fermentation	24 hrs	2	Fri - Sat	3 Fri - Sat
	5	Heat Exchange	1 hr	2	Sat	3 Sat
	6	Centrifugation	1hr	2	Sat	3 Sat

Unit Operation 7 pools the harvests from the three fermentation cycles above

7	Pool Harvests	3 hr	3	Mon	4 Mon

Unit Operations 8-9 undergo three repetative cycles per batch as set before continuing with unit operation 11
This translates to three consecutive passes through cell disruptor (unit op 9) with its associated heat exchangers (unit op 8 & 10) at the inlet and the outlet of the cell disruptor

1/3 disruption cycles per batch					
8	Heat Exchange				
9	Cell Disruption				
10	Heat Exchange	0.5 hr	3	Mon	4 Mon
2/3 disruption cycles per batch					
8	Heat Exchange				
9	Cell Disruption				
10	Heat Exchange	0.5 hr	3	Mon	4 Mon
3/3 disruption cycles per batch					
8	Heat Exchange				
9	Cell Disruption				
10	Heat Exchange	0.5 hr	3	Mon	4 Mon

FIG. 10

Sample Application of Process Design Cycles in Process Scheduling

Icrobial Fermentation Process (see unit operation list)

			First Process Cycle		Second Process Cycle	
		Duration	Week	Day	Week	Day
Unit ops 11-12 undergo two repetative cycles per batch as a set before continuing with unit op 13 This translates to two cycles of resuspending the cell lysate from the cell disruptor in a mild surfactant and reconcentrating the insoluble product to a paste by centrifugation						
½ product washing cylces per batch						
11	Resuspension	0.5 hr	3	Mon	4	Mon
12	Centrifugation	1 hr	3	Mon	4	Mon
2/3 product washing cylces per batch						
11	Resuspension	0.5 hr	3	Mon	4	Mon
12	Centrifugation	1 hr	3	Mon	4	Mon
Unit ops 13-22 undergo only one cylce per unit operation each to the end of the process						
13	Resuspension	0.5 hr	3	Mon	4	Mon
14	Buffer Exchange	2 hr	3	Mon	4	Mon
15	Filtratration	2 hr	3	Mon	4	Mon
16	Liquid Chromatography	16 hrs	3	Mon - Tue	4	Mon - Tue
17	Liquid Chromatography	4 hrs	3	Tue	4	Tue
18	Buffer Exchange	2 hrs	3	Tue	4	Tue
19	Liquid Chromatography	2 hrs	3	Wed	4	Wed
20	Buffer Exchange	2 hrs	3	Wed	4	Wed
21	Liquid Chromatography	2 hrs	3	Wed	4	Wed
22	Filtratration	2 hrs	3	Wed	4	Wed

FIG. 11

Process Time Line

	Operation	Duration (Hrs.) Calc.	A/D	Adj.	Rel. Time Scale (Hrs) Prep	Exec.	Compl.	Abs. Days Start	End	Start Date	Start Time	Finish Date	Finish Time	Calculations
1	1 A Inoculum Prep					15.5				06/03/96	08:00 AM			
2														
3	Set Up	3.0	0.0	3.0 Hrs	12.5			0.40	0.52	06/03/96	09:30 AM	06/03/96	12:30 PM	
4	Preincubation	3.0	0.0	3.0 Hrs	15.5			0.52	0.65	06/03/96	12:30 PM	06/03/96	03:30 PM	
5	Incubation	23.0	0.0	23.0 Hrs		38.5		0.65	1.60	06/03/96	03:30 PM	06/04/96	02:30 PM	
6	Clean Up	0.3	0.0	0.3 Hrs			38.8	1.60	1.61	06/04/96	02:30 PM	06/04/96	02:45 PM	
6	Subtotal	29.0		29.0 Hrs		38.5								
7														
8	2 A Flask Growth													
9														
10	Set Up	1.0	0.0	1.0 Hrs	37.5			1.52	1.56	06/04/96	12:30 PM	06/04/96	01:30 PM	
11	Preincubation	1.0	0.0	1.0 Hrs	38.5			1.56	1.60	06/04/96	01:30 PM	06/04/96	02:30 PM	
12	Incubation	23.0	0.0	23.0 Hrs		61.5		1.60	2.56	06/04/96	02:30 PM	06/05/96	01:30 PM	
13	Clean Up	0.3	0.0	0.3 Hrs			61.8	2.56	2.57	06/05/96	01:30 PM	06/05/96	01:45 PM	
13	Subtotal	25.0		25.0 Hrs		61.5								
14														
15	3 A Seed Fermentation													
16														
17	Set Up	1.0	0.0	1.0 Hrs	60.5			2.48	2.52	06/05/96	11:30 AM	06/05/96	12:30 PM	
18	Preincubation	1.0	0.0	1.0 Hrs	61.5			2.52	2.56	06/05/96	12:30 PM	06/05/96	01:30 PM	
19	Fermentation	21.0	0.0	21.0 Hrs		82.5		2.56	3.44	06/05/96	01:30 PM	06/06/96	10:30 AM	
20	Harvest	0.5	0.0	0.5 Hrs		83.0		3.44	3.46	06/06/96	10:30 AM	06/06/96	11:00 AM	50.0 L 1.7 LPM = 0.50 Hrs
21	CIP	1.0	0.0	1.0 Hrs			83.5	3.44	3.48	06/06/96	10:30 AM	06/06/96	11:30 AM	
22	SIP	1.0	0.0	1.0 Hrs			84.5	3.48	3.52	06/06/96	11:30 AM	06/06/96	12:30 PM	
23	Clean Up	3.0	0.0	3.0 Hrs			87.5	3.52	3.65	06/06/96	12:30 PM	06/06/96	03:30 PM	
24	Subtotal	28.5		28.5 Hrs		83.0								
25														
26	4 A Production Fermentation													
27														
28	Set Up	1.0	0.0	1.0 Hrs	82.0			3.38	3.42	06/06/96	09:00 AM	06/06/96	10:00 AM	
29	Preincubation	1.0	0.0	1.0 Hrs	83.0			3.42	3.46	06/06/96	10:00 AM	06/06/96	11:00 AM	
30	Fermentation	21.0	0.0	21.0 Hrs		104.0		3.46	4.33	06/06/96	11:00 AM	06/07/96	08:00 AM	
31	CIP	1.0	0.0	1.0 Hrs			105.0	4.33	4.38	06/07/96	08:00 AM	06/07/96	09:00 AM	
32	SIP	1.0	0.0	1.0 Hrs			106.0	4.38	4.42	06/07/96	09:00 AM	06/07/96	10:00 AM	
33	Clean Up	2.0	0.0	2.0 Hrs			108.0	4.42	4.50	06/07/96	10:00 AM	06/07/96	12:00 PM	
34	Subtotal	27.0		27.0 Hrs		104.0								
35														
36	6 A Heat Exchange													
37														
38	Set Up	0.50	0.0	0.5 Hrs	104.5			4.33	4.35	06/07/96	08:00 AM	06/07/96	08:30 AM	
39	Transfer	1.00	0.0	1.0 Hrs		105.0		4.33	4.38	06/07/96	08:00 AM	06/07/96	09:00 AM	562.1 L @ 9.4 LPM = 1.00 Hrs
40	CIP	1.0	0.0	1.0 Hrs			106.0	4.38	4.42	06/07/96	09:00 AM	06/07/96	10:00 AM	
41	SIP	1.0	0.0	1.0 Hrs			107.0	4.42	4.46	06/07/96	10:00 AM	06/07/96	11:00 AM	
42	Clean Up	2.0	0.0	2.0 Hrs			109.0	4.46	4.54	06/07/96	11:00 AM	06/07/96	01:00 PM	
43	Subtotal	5.0		5.0 Hrs		105.0								
44														
45	6 A Cont. Cent./Solids													
46														
47	Set Up	1.00	0.0	1.0 Hrs	105.0			4.33	4.38	06/07/96	08:00 AM	06/07/96	09:00 AM	
48	Centrifugation	1.00	0.0	1.0 Hrs		106.0		4.38	4.42	06/07/96	09:00 AM	06/07/96	10:00 AM	562.1 L @ 9.4 LPM = 1.00 Hrs
49	Wash	0.10	0.0	0.1 Hrs		106.1		4.42	4.42	06/07/96	10:00 AM	06/07/96	10:06 AM	1.0 L @ 0.2 LPM = 0.10 Hrs
50	CIP	0.25	0.0	0.3 Hrs			106.4	4.42	4.43	06/07/96	10:06 AM	06/07/96	10:21 AM	20.0 L @ 1.3 LPM = 0.25 Hrs
51	SIP	1.00	0.0	1.0 Hrs			107.4	4.43	4.47	06/07/96	10:21 AM	06/07/96	11:21 AM	
52	Clean Up	0.50	0.0	0.5 Hrs			107.9	4.47	4.49	06/07/96	11:21 AM	06/07/96	11:51 AM	
53	Sub Total	3.85		3.85 Hrs		106.1								
54														
55	1 B Inoculum Prep													
56														
57	Set Up	1.0	0.0	1.0 Hrs	14.5			0.58	0.60	06/03/96	01:30 PM	06/03/96	02:30 PM	
58	Preincubation	1.0	0.0	1.0 Hrs	15.5			0.60	0.65	06/03/96	02:30 PM	06/03/96	03:30 PM	

1 2 3 4 5 6 7 8 9 10 11 12 13 14 15

FIG. 12A

		Process Time Line												
		Duration (Hrs.)			Rel. Time Scale (Hrs)			Abs. Days		Start		Finish		
	Operation	Calc.	A/D	Adj.	Prep	Exec.	Compl.	Start	End	Date	Time	Date	Time	Calculations
						15.5				06/03/96	08:00 AM			
59	Incubation	23.0	0.0	23.0 Hrs		38.5		0.65	1.60	06/03/96	03:30 PM	06/04/96	02:30 PM	
60	Clean Up	0.3	0.0	0.3 Hrs			38.8	1.60	1.61	06/04/96	02:30 PM	06/04/96	02:45 PM	
60	Subtotal	25.0		25.0 Hrs		38.5								
61														
62	2 B Flask Growth													
63														
64	Set Up	1.0	0.0	1.0 Hrs	37.5			1.52	1.56	06/04/96	12:30 PM	06/04/96	01:30 PM	
65	Preincubation	1.0	0.0	1.0 Hrs	38.5			1.56	1.60	06/04/96	01:30 PM	06/04/96	02:30 PM	
66	Incubation	23.0	0.0	23.0 Hrs		61.5		1.60	2.56	06/04/96	02:30 PM	06/05/96	01:30 PM	
67	Clean Up	0.3	0.0	0.3 Hrs			61.8	2.56	2.57	06/05/96	01:30 PM	06/05/96	01:45 PM	
67	Subtotal	25.0		25.0 Hrs		61.5								
68														
69	3 B Seed Fermentation													
70														
71	Set Up	1.0	0.0	1.0 Hrs	60.5			2.48	2.52	06/05/96	11:30 AM	06/05/96	12:30 PM	
72	Preincubation	1.0	0.0	1.0 Hrs	61.5			2.52	2.56	06/05/96	12:30 PM	06/05/96	01:30 PM	
73	Fermentation	21.0	0.0	21.0 Hrs		82.5		2.56	3.44	06/05/96	01:30 PM	06/06/96	10:30 AM	
74	Harvest	0.5	0.0	0.5 Hrs		83.0		3.44	3.46	06/06/96	10:30 AM	06/06/96	11:00 AM	50.0 L 1.7 LPM = 0.50 Hrs
75	CIP	1.0	0.0	1.0 Hrs			83.5	3.44	3.48	06/06/96	10:30 AM	06/06/96	11:30 AM	
76	SIP	1.0	0.0	1.0 Hrs			84.5	3.48	3.52	06/06/96	11:30 AM	06/06/96	12:30 PM	
77	Clean Up	3.0	0.0	3.0 Hrs			87.5	3.52	3.65	06/06/96	12:30 PM	06/06/96	03:30 PM	
78	Subtotal	28.5		28.5 Hrs		83.0								
79														
80	4 B Production Fermentation													
81														
82	Set Up	1.0	0.0	1.0 Hrs	82.0			3.38	3.42	06/06/96	09:00 AM	06/06/96	10:00 AM	
83	Preincubation	1.0	0.0	1.0 Hrs	83.0			3.42	3.46	06/06/96	10:00 AM	06/06/96	11:00 AM	
84	Fermentation	21.0	0.0	21.0 Hrs		104.0		3.46	4.33	06/06/96	11:00 AM	06/07/96	08:00 AM	
85	CIP	1.0	0.0	1.0 Hrs			105.0	4.33	4.38	06/07/96	08:00 AM	06/07/96	09:00 AM	
86	SIP	1.0	0.0	1.0 Hrs			106.0	4.38	4.42	06/07/96	09:00 AM	06/07/96	10:00 AM	
87	Clean Up	2.0	0.0	2.0 Hrs			108.0	4.42	4.50	06/07/96	10:00 AM	06/07/96	12:00 PM	
88	Subtotal	27.0		27.0 Hrs		104.0								
89														
90	6 B Heat Exchange													
91														
92	Set Up	0.50	0.0	0.5 Hrs	104.5			4.33	4.35	06/07/96	08:00 AM	06/07/96	08:30 AM	
93	Transfer	1.00	0.0	1.0 Hrs		105.0		4.33	4.38	06/07/96	08:00 AM	06/07/96	09:00 AM	562.1 L @ 9.4 LPM = 1.00 Hrs
94	CIP	1.0	0.0	1.0 Hrs			106.0	4.38	4.42	06/07/96	09:00 AM	06/07/96	10:00 AM	
95	SIP	1.0	0.0	1.0 Hrs			107.0	4.42	4.46	06/07/96	10:00 AM	06/07/96	11:00 AM	
96	Clean Up	2.0	0.0	2.0 Hrs			109.0	4.46	4.54	06/07/96	11:00 AM	06/07/96	01:00 PM	
97	Subtotal	5.0		5.0 Hrs		105.0								
98														
99	6 B Cont. Cent/Solids													
100														
101	Set Up	1.00	0.0	1.0 Hrs	105.0			4.33	4.38	06/07/96	08:00 AM	06/07/96	09:00 AM	
102	Centrifugation	1.00	0.0	1.0 Hrs		106.0		4.38	4.42	06/07/96	09:00 AM	06/07/96	10:00 AM	562.1 L @ 9.4 LPM = 1.00 Hrs
103	Wash	0.10	0.0	0.1 Hrs		106.1		4.42	4.42	06/07/96	10:00 AM	06/07/96	10:06 AM	1.0 L @ 0.2 LPM = 0.10 Hrs
104	CIP	0.25	0.0	0.3 Hrs			106.4	4.42	4.43	06/07/96	10:06 AM	06/07/96	10:21 AM	20.0 L @ 1.3 LPM = 0.25 Hrs
105	SIP	1.00	0.0	1.0 Hrs			107.4	4.43	4.47	06/07/96	10:21 AM	06/07/96	11:21 AM	
106	Clean Up	0.50	0.0	0.5 Hrs			107.9	4.47	4.49	06/07/96	11:21 AM	06/07/96	11:51 AM	
107	Sub Total	3.85		3.85 Hrs		106.1								
108														
109	1 C Inoculum Prep													
110														
111	Set Up	1.0	0.0	1.0 Hrs	14.5			0.56	0.60	06/03/96	01:30 PM	06/03/96	02:30 PM	
112	Preincubation	1.0	0.0	1.0 Hrs	15.5			0.60	0.65	06/03/96	02:30 PM	06/03/96	03:30 PM	
13	Incubation	23.0	0.0	23.0 Hrs		38.5		0.65	1.60	06/03/96	03:30 PM	06/04/96	02:30 PM	
14	Clean Up	0.3	0.0	0.3 Hrs			38.8	1.60	1.61	06/04/96	02:30 PM	06/04/96	02:45 PM	
114	Subtotal	25.0		25.0 Hrs		38.5								
115														

FIG. 12B

Process Time Line

	Operation	Duration (Hrs.) Calc.	A/D	Adj.	Rel. Time Scale (Hrs) Prep	Exec.	Compl.	Abs. Days Start	End	Start Date	Start Time	Finish Date	Finish Time	Calculations
116	2 C Flask Growth					15.5				06/03/96	08:00 AM			
117														
118	Set Up	1.0	0.0	1.0 Hrs	37.5			1.52	1.56	06/04/96	12:30 PM	06/04/96	01:30 PM	
119	Preincubation	1.0	0.0	1.0 Hrs	38.5			1.56	1.60	06/04/96	01:30 PM	06/04/96	02:30 PM	
120	Incubation	23.0	0.0	23.0 Hrs		61.5		1.60	2.56	06/04/96	02:30 PM	06/05/96	01:30 PM	
121	Clean Up	0.3	0.0	0.3 Hrs			61.8	2.56	2.57	06/05/96	01:30 PM	06/05/96	01:45 PM	
121	Subtotal	25.0		25.0 Hrs		61.5								
122														
123	3 C Seed Fermentation													
124														
125	Set Up	1.0	0.0	1.0 Hrs	60.5			2.48	2.52	06/05/96	11:30 AM	06/05/96	12:30 PM	
126	Preincubation	1.0	0.0	1.0 Hrs	61.5			2.52	2.56	06/05/96	12:30 PM	06/05/96	01:30 PM	
127	Fermentation	21.0	0.0	21.0 Hrs		82.5		2.56	3.44	06/05/96	01:30 PM	06/06/96	10:30 AM	
128	Harvest	0.5	0.0	0.5 Hrs		83.0		3.44	3.46	06/06/96	10:30 AM	06/06/96	11:00 AM	50.0 L 1.7 LPM = 0.50 Hrs
129	CIP	1.0	0.0	1.0 Hrs			83.5	3.44	3.48	06/06/96	10:30 AM	06/06/96	11:30 AM	
130	SIP	1.0	0.0	1.0 Hrs			84.5	3.48	3.52	06/06/96	11:30 AM	06/06/96	12:30 PM	
131	Clean Up	3.0	0.0	3.0 Hrs			87.5	3.52	3.65	06/06/96	12:30 PM	06/06/96	03:30 PM	
132	Subtotal	28.5		28.5 Hrs		83.0								
133														
134	4 C Production Fermentation													
135														
136	Set Up	1.0	0.0	1.0 Hrs	82.0			3.38	3.42	06/06/96	09:00 AM	06/06/96	10:00 AM	
137	Preincubation	1.0	0.0	1.0 Hrs	83.0			3.42	3.46	06/06/96	10:00 AM	06/06/96	11:00 AM	
138	Fermentation	21.0	0.0	21.0 Hrs		104.0		3.46	4.33	06/06/96	11:00 AM	06/07/96	08:00 AM	
139	CIP	1.0	0.0	1.0 Hrs			105.0	4.33	4.38	06/07/96	08:00 AM	06/07/96	09:00 AM	
140	SIP	1.0	0.0	1.0 Hrs			106.0	4.38	4.42	06/07/96	09:00 AM	06/07/96	10:00 AM	
141	Clean Up	2.0	0.0	2.0 Hrs			108.0	4.42	4.50	06/07/96	10:00 AM	06/07/96	12:00 PM	
142	Subtotal	27.0		27.0 Hrs		104.0								
143														
144	5 C Heat Exchange													
145														
146	Set Up	0.50	0.0	0.5 Hrs	104.5			4.33	4.35	06/07/96	08:00 AM	06/07/96	08:30 AM	
147	Transfer	1.00	0.0	1.0 Hrs		105.0		4.33	4.38	06/07/96	08:00 AM	06/07/96	09:00 AM	562.1 L @ 9.4 LPM = 1.00 Hrs
148	CIP	1.0	0.0	1.0 Hrs			106.0	4.38	4.42	06/07/96	09:00 AM	06/07/96	10:00 AM	
149	SIP	1.0	0.0	1.0 Hrs			107.0	4.42	4.46	06/07/96	10:00 AM	06/07/96	11:00 AM	
150	Clean Up	2.0	0.0	2.0 Hrs			109.0	4.46	4.54	06/07/96	11:00 AM	06/07/96	01:00 PM	
151	Subtotal	5.0		5.0 Hrs		105.0								
152														
153	6 C Cont. Cent./Solids													
154														
155	Set Up	1.00	0.0	1.0 Hrs	105.0			4.33	4.38	06/07/96	08:00 AM	06/07/96	09:00 AM	
156	Centrifugation	1.00	0.0	1.0 Hrs		106.0		4.38	4.42	06/07/96	09:00 AM	06/07/96	10:00 AM	562.1 L @ 9.4 LPM = 1.00 Hrs
157	Wash	0.10	0.0	0.1 Hrs		106.1		4.42	4.42	06/07/96	10:00 AM	06/07/96	10:06 AM	1.0 L @ 0.2 LPM = 0.10 Hrs
158	CIP	0.25	0.0	0.3 Hrs			106.4	4.42	4.43	06/07/96	10:06 AM	06/07/96	10:21 AM	20.0 L @ 1.3 LPM = 0.25 Hrs
159	SIP	1.00	0.0	1.0 Hrs			107.4	4.43	4.47	06/07/96	10:21 AM	06/07/96	11:21 AM	
160	Clean Up	0.50	0.0	0.5 Hrs			107.9	4.47	4.49	06/07/96	11:21 AM	06/07/96	11:51 AM	
161	Sub Total	3.85		3.85 Hrs		106.1								
162														
163	7 A Resolubilization													
164														
165	Set Up	1.00	0.0	1.0 Hrs	106.1			4.38	4.42	06/07/96	09:06 AM	06/07/96	10:06 AM	
166	Dilution	0.50	0.0	0.5 Hrs		106.6		4.42	4.44	06/07/96	10:06 AM	06/07/96	10:36 AM	46.7 L @ 1.6 LPM = 0.50 Hrs.
167	Agitate	1.00	0.0	1.0 Hrs		107.6		4.44	4.48	06/07/96	10:36 AM	06/07/96	11:36 AM	0.50 Hrs.
168	CIP	1.00	0.0	1.0 Hrs			108.6	4.48	4.53	06/07/96	11:36 AM	06/07/96	12:36 PM	
169	SIP	1.00	0.0	1.0 Hrs			109.6	4.53	4.57	06/07/96	12:36 PM	06/07/96	01:36 PM	
170	Clean Up	1.00	0.0	1.0 Hrs			110.6	4.57	4.61	06/07/96	01:36 PM	06/07/96	02:36 PM	
171	Subtotal	5.50		5.50 Hrs		107.6								
172														
173	8 A Heat Exchange													
174														

FIG. 12C

	Operation	Process Time Line: Duration (Hrs.) Calc.	A/D	Adj.	Rel. Time Scale (Hrs) Prep	Exec.	Compl.	Abs. Days Start	End	Start Date	Start Time	Finish Date	Finish Time	Calculations
						15.5				06/03/96	08:00 AM			
176	Set Up	0.50	0.0	0.5 Hrs	107.6			4.46	4.48	06/07/96	11:06 AM	06/07/96	11:36 AM	
176	Transfer	0.30	0.0	0.3 Hrs		107.9		4.48	4.50	06/07/96	11:36 AM	06/07/96	11:54 AM	66.5 L @ 3.7 LPM = 0.30 Hrs
177	CIP	0.0	0.0	0.0 Hrs			107.9	4.50	4.50	06/07/96	11:54 AM	06/07/96	11:54 AM	
178	SIP	0.0	0.0	0.0 Hrs			107.9	4.50	4.50	06/07/96	11:54 AM	06/07/96	11:54 AM	
179	Clean Up	0.0	0.0	0.0 Hrs			107.9	4.50	4.50	06/07/96	11:54 AM	06/07/96	11:54 AM	
180	Subtotal	0.8		0.8 Hrs		107.9								
181														
182	9 A Hommogenization													
183														
184	Set Up	0.25	0.0	0.3 Hrs	107.9			4.49	4.50	06/07/96	11:39 AM	06/07/96	11:54 AM	
185	Lysis	0.68	0.0	0.7 Hrs		108.6		4.50	4.52	06/07/96	11:54 AM	06/07/96	12:34 PM	66.5 L @ 1.6 LPM = 0.68 Hrs
186	CIP	0.0	0.0	0.0 Hrs			108.6	4.52	4.52	06/07/96	12:34 PM	06/07/96	12:34 PM	
187	SIP	0.0	0.0	0.0 Hrs			108.6	4.52	4.52	06/07/96	12:34 PM	06/07/96	12:34 PM	
188	Clean Up	0.0	0.0	0.0 Hrs			108.6	4.52	4.52	06/07/96	12:34 PM	06/07/96	12:34 PM	
189	Sub Total	0.9		0.9 Hrs		108.6								
190														
191	10 A Heat Exchange													
192														
193	Set Up	0.50	0.0	0.5 Hrs	108.6			4.50	4.52	06/07/96	12:04 PM	06/07/96	12:34 PM	
194	Transfer	0.30	0.0	0.3 Hrs		108.9		4.52	4.54	06/07/96	12:34 PM	06/07/96	12:52 PM	69.0 L @ 3.8 LPM = 0.30 Hrs
195	CIP	0.0	0.0	0.0 Hrs			108.9	4.54	4.54	06/07/96	12:52 PM	06/07/96	12:52 PM	
196	SIP	0.0	0.0	0.0 Hrs			108.9	4.54	4.54	06/07/96	12:52 PM	06/07/96	12:52 PM	
197	Clean Up	0.0	0.0	0.0 Hrs			108.9	4.54	4.54	06/07/96	12:52 PM	06/07/96	12:52 PM	
198	Subtotal	0.8		0.8 Hrs		108.9								
199														
200	8 B Heat Exchange													
201														
202	Set Up	0.00	0.0	0.0 Hrs	108.9			4.54	4.54	06/07/96	12:52 PM	06/07/96	12:52 PM	
203	Transfer	0.30	0.0	0.3 Hrs		109.2		4.54	4.55	06/07/96	12:52 PM	06/07/96	01:10 PM	66.5 L @ 3.7 LPM = 0.30 Hrs
204	CIP	0.0	0.0	0.0 Hrs			109.2	4.55	4.55	06/07/96	01:10 PM	06/07/96	01:10 PM	
205	SIP	0.0	0.0	0.0 Hrs			109.2	4.55	4.55	06/07/96	01:10 PM	06/07/96	01:10 PM	
206	Clean Up	0.0	0.0	0.0 Hrs			109.2	4.55	4.55	06/07/96	01:10 PM	06/07/96	01:10 PM	
207	Subtotal	0.3		0.3 Hrs		109.2								
208														
209	9 B Hommogenization													
210														
211	Set Up	0.00	0.0	0.0 Hrs	109.2			4.55	4.55	06/07/96	01:10 PM	06/07/96	01:10 PM	
212	Lysis	0.68	0.0	0.7 Hrs		109.9		4.55	4.58	06/07/96	01:10 PM	06/07/96	01:51 PM	66.5 L @ 1.6 LPM = 0.68 Hrs
213	CIP	0.0	0.0	0.0 Hrs			109.9	4.58	4.58	06/07/96	01:51 PM	06/07/96	01:51 PM	
214	SIP	0.0	0.0	0.0 Hrs			109.9	4.58	4.58	06/07/96	01:51 PM	06/07/96	01:51 PM	
215	Clean Up	0.0	0.0	0.0 Hrs			109.9	4.58	4.58	06/07/96	01:51 PM	06/07/96	01:51 PM	
216	Sub Total	0.7		0.7 Hrs		109.9								
217														
218	10 B Heat Exchange													
219														
220	Set Up	0.50	0.0	0.5 Hrs	109.9			4.56	4.58	06/07/96	01:21 PM	06/07/96	01:51 PM	
221	Transfer	0.30	0.0	0.3 Hrs		110.2		4.58	4.59	06/07/96	01:51 PM	06/07/96	02:09 PM	69.0 L @ 3.8 LPM = 0.30 Hrs
222	CIP	0.0	0.0	0.0 Hrs			110.2	4.59	4.59	06/07/96	02:09 PM	06/07/96	02:09 PM	
223	SIP	0.0	0.0	0.0 Hrs			110.2	4.59	4.59	06/07/96	02:09 PM	06/07/96	02:09 PM	
224	Clean Up	0.0	0.0	0.0 Hrs			110.2	4.59	4.59	06/07/96	02:09 PM	06/07/96	02:09 PM	
225	Subtotal	0.8		0.8 Hrs		110.2								
226														
227	8 C Heat Exchange													
228														
229	Set Up	0.00	0.0	0.0 Hrs	110.2			4.59	4.59	06/07/96	02:09 PM	06/07/96	02:09 PM	
230	Transfer	0.30	0.0	0.3 Hrs		110.5		4.59	4.60	06/07/96	02:09 PM	06/07/96	02:27 PM	66.5 L @ 3.7 LPM = 0.30 Hrs
231	CIP	1.0	0.0	1.0 Hrs			111.5	4.60	4.64	06/07/96	02:27 PM	06/07/96	03:27 PM	
232	SIP	1.0	0.0	1.0 Hrs			112.5	4.64	4.69	06/07/96	03:27 PM	06/07/96	04:27 PM	
233	Clean Up	1.0	0.0	1.0 Hrs			113.5	4.69	4.73	06/07/96	04:27 PM	06/07/96	05:27 PM	
234	Subtotal	3.3		3.3 Hrs		110.5								

FIG. 12D

	Operation	Process Time Line: Duration (Hrs.) Calc.	A/D	Adj.	Rel. Time Scale (Hrs) Prep	Exec.	Compl.	Abs. Days Start	End	Start Date	Start Time	Finish Date	Finish Time	Calculations
235						15.5				06/03/96	08:00 AM			
236	9 C Hommogenization													
237														
238	Set Up	0.00	0.0	0.0 Hrs	110.5			4.60	4.60	06/07/96	02:27 PM	06/07/96	02:27 PM	
239	Lysis	0.68	0.0	0.7 Hrs		111.1		4.60	4.63	06/07/96	02:27 PM	06/07/96	03:07 PM	66.5 L @ 1.6 LPM = 0.68 Hrs
240	CIP	1.0	0.0	1.0 Hrs			112.1	4.63	4.67	06/07/96	03:07 PM	06/07/96	04:07 PM	
241	SIP	1.0	0.0	1.0 Hrs			113.1	4.67	4.71	06/07/96	04:07 PM	06/07/96	05:07 PM	
242	Clean Up	1.0	0.0	1.0 Hrs			114.1	4.71	4.76	06/07/96	05:07 PM	06/07/96	06:07 PM	
243	Sub Total	3.7		3.7 Hrs		111.1								
244														
245	10 C Heat Exchange													
246														
247	Set Up	0.00	0.0	0.0 Hrs	111.1			4.63	4.63	06/07/96	03:07 PM	06/07/96	03:07 PM	
248	Transfer	0.30	0.0	0.3 Hrs		111.4		4.63	4.64	06/07/96	03:07 PM	06/07/96	03:25 PM	69.0 L @ 3.8 LPM = 0.30 Hrs
249	CIP	1.0	0.0	1.0 Hrs			112.4	4.64	4.68	06/07/96	03:25 PM	06/07/96	04:25 PM	
250	SIP	1.0	0.0	1.0 Hrs			113.4	4.68	4.73	06/07/96	04:25 PM	06/07/96	05:25 PM	
251	Clean Up	1.0	0.0	1.0 Hrs			114.4	4.73	4.77	06/07/96	05:25 PM	06/07/96	06:25 PM	
252	Subtotal	3.3		3.3 Hrs		111.4								
253														
254	11 A Resolubilization													
255														
256	Set Up	1.0	0.0	1.0 Hrs	108.9			4.49	4.54	06/07/96	11:52 AM	06/07/96	12:52 PM	
257	Dilution	0.5	0.0	0.5 Hrs		109.4		4.54	4.56	06/07/96	12:52 PM	06/07/96	01:22 PM	206.9 L @ 6.9 LPM = 0.50 Hrs.
258	Agitate	0.5	0.0	0.5 Hrs		109.9		4.56	4.58	06/07/96	01:22 PM	06/07/96	01:52 PM	0.50 Hrs.
259	CIP	0.0	0.0	0.0 Hrs			109.9	4.58	4.58	06/07/96	01:52 PM	06/07/96	01:52 PM	
260	SIP	0.0	0.0	0.0 Hrs			109.9	4.58	4.58	06/07/96	01:52 PM	06/07/96	01:52 PM	
261	Clean Up	0.0	0.0	0.0 Hrs			109.9	4.58	4.58	06/07/96	01:52 PM	06/07/96	01:52 PM	
262	Subtotal	2.0		2.0 Hrs		109.9								
263														
264	12 A Cont. Cent./Solids													
265														
266	Set Up	1.0	0.0	1.0 Hrs	109.9			4.54	4.58	06/07/96	12:52 PM	06/07/96	01:52 PM	
267	Centrifugation	0.5	0.0	0.5 Hrs		110.4		4.58	4.60	06/07/96	01:52 PM	06/07/96	02:22 PM	275.9 L @ 9.2 LPM = 0.50 Hrs
268	Wash	0.1	0.0	0.1 Hrs		110.5		4.60	4.60	06/07/96	02:22 PM	06/07/96	02:28 PM	3.0 L @ 0.5 LPM = 0.10 Hrs
269	CIP	0.0	0.0	0.0 Hrs			110.5	4.60	4.60	06/07/96	02:28 PM	06/07/96	02:28 PM	8.0 L @ 0.5 LPM = 0.25 Hrs
270	SIP	0.0	0.0	0.0 Hrs			110.5	4.60	4.60	06/07/96	02:28 PM	06/07/96	02:28 PM	
271	Clean Up	0.0	0.0	0.0 Hrs			110.5	4.60	4.60	06/07/96	02:28 PM	06/07/96	02:28 PM	
272	Sub Total	1.6		1.6 Hrs		110.5								
273														
274	11 B Resolubilization													
275														
276	Set Up	0.0	0.0	0.0 Hrs	110.5			4.60	4.60	06/07/96	02:28 PM	06/07/96	02:28 PM	
277	Dilution	0.5	0.0	0.5 Hrs		111.0		4.60	4.62	06/07/96	02:28 PM	06/07/96	02:58 PM	206.9 L @ 6.9 LPM = 0.50 Hrs.
278	Agitate	0.3	0.0	0.3 Hrs		111.2		4.62	4.63	06/07/96	02:58 PM	06/07/96	03:13 PM	0.50 Hrs.
279	CIP	1.0	0.0	1.0 Hrs			112.2	4.63	4.68	06/07/96	03:13 PM	06/07/96	04:13 PM	
280	SIP	1.0	0.0	1.0 Hrs			113.2	4.68	4.72	06/07/96	04:13 PM	06/07/96	05:13 PM	
281	Clean Up	1.0	0.0	1.0 Hrs			114.2	4.72	4.76	06/07/96	05:13 PM	06/07/96	06:13 PM	
282	Subtotal	3.8		3.8 Hrs		111.2								
283														
284	12 B Cont. Cent./Solids													
285														
286	Set Up	1.0	0.0	1.0 Hrs	111.2			4.59	4.63	06/07/96	02:13 PM	06/07/96	03:13 PM	
287	Centrifugation	0.5	0.0	0.5 Hrs		111.7		4.63	4.66	06/07/96	03:13 PM	06/07/96	03:43 PM	275.9 L @ 9.2 LPM = 0.50 Hrs
288	Wash	0.1	0.0	0.1 Hrs		111.8		4.66	4.66	06/07/96	03:43 PM	06/07/96	03:49 PM	3.0 L @ 0.5 LPM = 0.10 Hrs
289	CIP	0.3	0.0	0.3 Hrs			112.1	4.66	4.67	06/07/96	03:49 PM	06/07/96	04:04 PM	8.0 L @ 0.5 LPM = 0.25 Hrs
290	SIP	1.0	0.0	1.0 Hrs			113.1	4.67	4.71	06/07/96	04:04 PM	06/07/96	05:04 PM	
291	Clean Up	0.5	0.0	0.5 Hrs			113.6	4.71	4.73	06/07/96	05:04 PM	06/07/96	05:34 PM	
292	Sub Total	3.4		3.4 Hrs		111.6								
293														
294	13 A Resolubilization													

FIG. 12E

	Operation	Process Time Line: Duration (Hrs.) Calc.	A/D	Adj.	Rel. Time Scale (Hrs.) Prep	Exec.	Compl.	Abs. Days: Start	End	Start: Date	Time	Finish: Date	Time	Calculations
295						15.5				06/03/96	08:00 AM			
296	Set Up	1.0	0.0	1.0 Hrs	110.5			4.56	4.60	06/07/96	01:28 PM	06/07/96	02:28 PM	
297	Dilution	0.5	0.0	0.5 Hrs		111.0		4.60	4.62	06/07/96	02:28 PM	06/07/96	02:58 PM	60.7 L @ 2.0 LPM = 0.50 Hrs.
298	Agitate	18.0	0.0	18.0 Hrs		129.0		4.62	5.37	06/07/96	02:58 PM	06/08/96	08:58 AM	23.50 Hrs.
299	CIP	1.0	0.0	1.0 Hrs			130.0	5.37	5.42	06/08/96	08:58 AM	06/08/96	09:58 AM	
300	SIP	1.0	0.0	1.0 Hrs			131.0	5.42	5.46	06/08/96	09:58 AM	06/08/96	10:58 AM	
301	Clean Up	1.0	0.0	1.0 Hrs			132.0	5.46	5.50	06/08/96	10:58 AM	06/08/96	11:58 AM	
302	Subtotal	22.5		22.5 Hrs		129.0								
303														
304	14 A Concentration													
305														
306	Set Up	1.0	0.0	1.0 Hrs	127.6			5.28	5.32	06/08/96	06:38 AM	06/08/96	07:38 AM	26.99 SF
307	Flush	0.7	0.0	0.7 Hrs	128.3			5.32	5.35	06/08/96	07:38 AM	06/08/96	08:18 AM	
308	Prime	0.7	0.0	0.7 Hrs	129.0			5.35	5.37	06/08/96	08:18 AM	06/08/96	08:58 AM	54.0 L @ 3.0 L/SF/Hr or 1.35 LPM
309	Concentration	1.0	0.0	1.0 Hrs		130.0		5.37	5.42	06/08/96	08:58 AM	06/08/96	09:58 AM	54.0 L @ 3.0 L/SF/Hr or 1.35 LPM
310	Dilution	0.4	0.0	0.4 Hrs		130.4		5.42	5.43	06/08/96	09:58 AM	06/08/96	10:25 AM	81.0 L @ 3.0 L/SF/Hr or 1.35 LPM
311	Wash	0.9	0.0	0.9 Hrs		131.3		5.43	5.47	06/08/96	10:25 AM	06/08/96	11:19 AM	13.5 L @ 0.5 LPM
312	Flush	0.3	0.0	0.3 Hrs			131.7	5.47	5.49	06/08/96	11:19 AM	06/08/96	11:39 AM	72.9 L @ 3.0 L/SF/Hr or 1.35 LPM
313	Store	0.7	0.0	0.7 Hrs			132.3	5.49	5.51	06/08/96	11:39 AM	06/08/96	12:19 PM	27.0 L @ 3.0 L/SF/Hr or 1.35 LPM
314	CIP	1.0	0.0	1.0 Hrs			133.3	5.51	5.56	06/08/96	12:19 PM	06/08/96	01:19 PM	54.0 L @ 3.0 L/SF/Hr or 1.35 LPM
315	SIP	1.0	0.0	1.0 Hrs			134.3	5.56	5.60	06/08/96	01:19 PM	06/08/96	02:19 PM	
316	Clean Up	1.0	0.0	1.0 Hrs			135.3	5.60	5.64	06/08/96	02:19 PM	06/08/96	03:19 PM	
317	Sub Total	8.7		8.7 Hrs		131.3								
318														Max FR 1.35 LPM
319	15 A Microfiltration													
320														12.60 SF
321	Set Up	1.0	0.0	1.0 Hrs	131.1			5.42	5.46	06/08/96	10:03 AM	06/08/96	11:03 AM	
22	Flush	0.1	0.0	0.1 Hrs	131.2			5.46	5.47	06/08/96	11:03 AM	06/08/96	11:11 AM	
23	Prime	0.1	0.0	0.1 Hrs	131.3			5.47	5.47	06/08/96	11:11 AM	06/08/96	11:19 AM	25.2 L @ 15.0 L/SF/Hr or 3.15 LPM
324	Filtration	0.5	0.0	0.5 Hrs		131.8		5.47	5.49	06/08/96	11:19 AM	06/08/96	11:49 AM	25.2 L @ 15.0 L/SF/Hr or 3.15 LPM
325	Wash	0.0	0.0	0.0 Hrs		131.8		5.49	5.49	06/08/96	11:49 AM	06/08/96	11:49 AM	84.6 L @ 15.0 L/SF/Hr or 3.15 LPM
326	Regenerate	0.0	0.0	0.0 Hrs			131.9	5.49	5.49	06/08/96	11:49 AM	06/08/96	11:51 AM	0.0 L @ 15.0 L/SF/Hr or 3.15 LPM
327	Store	0.1	0.0	0.1 Hrs			131.9	5.49	5.50	06/08/96	11:51 AM	06/08/96	11:55 AM	6.3 L @ 15.0 L/SF/Hr or 3.15 LPM
328	CIP	1.0	0.0	1.0 Hrs			132.9	5.50	5.54	06/08/96	11:55 AM	06/08/96	12:55 PM	12.6 L @ 15.0 L/SF/Hr or 3.15 LPM
329	SIP	1.0	0.0	1.0 Hrs			133.9	5.54	5.58	06/08/96	12:55 PM	06/08/96	01:55 PM	
330	Clean Up	1.0	0.0	1.0 Hrs			134.9	5.58	5.62	06/08/96	01:55 PM	06/08/96	02:55 PM	
331	Sub Total	4.9		4.9 Hrs		131.8								
332														
333	16 A P/A MPLC													
334														63.6 L CV 0.4 H/D 60.32 CM Dia.
335	Equilibration	1.1	0.0	1.1 Hrs	131.4			5.43	5.48	06/08/96	10:17 AM	06/08/96	11:24 AM	
336	Load	0.7	0.0	0.7 Hrs		132.5		5.49	5.52	06/08/96	11:49 AM	06/08/96	12:31 PM	318.9 L @ 100.0 CM/HR or 4.76 LPM
337	Wash	1.3	0.0	1.3 Hrs		133.9		5.52	5.58	06/08/96	12:31 PM	06/08/96	01:52 PM	100.5 L @ 50.0 CM/HR or 2.38 LPM
338	Elute A	1.3	0.0	1.3 Hrs		135.2		5.58	5.63	06/08/96	01:52 PM	06/08/96	03:12 PM	191.4 L @ 50.0 CM/HR or 2.38 LPM
339	Elute B	0.0	0.0	0.0 Hrs		135.2		5.63	5.63	06/08/96	03:12 PM	06/08/96	03:12 PM	191.4 L @ 50.0 CM/HR or 2.38 LPM
340	Regenerate	0.2	0.0	0.2 Hrs			135.4	5.63	5.64	06/08/96	03:12 PM	06/08/96	03:25 PM	0.0 L @ 30.0 CM/HR or 1.43 LPM
341	Store	0.4	0.0	0.4 Hrs			135.9	5.64	5.66	06/08/96	03:25 PM	06/08/96	03:52 PM	63.8 L @ 100.0 CM/HR or 4.76 LPM
342	CIP	1.0	0.0	1.0 Hrs			136.9	5.66	5.70	06/08/96	03:52 PM	06/08/96	04:52 PM	127.6 L @ 100.0 CM/HR or 4.76 LPM
343	SIP	1.0	0.0	1.0 Hrs			137.9	5.70	5.74	06/08/96	04:52 PM	06/08/96	05:52 PM	
344	Clean Up	1.0	0.0	1.0 Hrs			138.9	5.74	5.79	06/08/96	05:52 PM	06/08/96	06:52 PM	
345	Sub Total	5.2		5.2 Hrs		135.2								
346														Max FR 4.76 LPM
347														
348	17 A P/A MPLC													
349														12.2 L CV 0.4 H/D 34.75 CM Dia.
350	Equilibration	0.6	0.0	0.6 Hrs	135.6			5.62	5.65	06/08/96	02:59 PM	06/08/96	03:38 PM	
51	Load	1.1	0.0	1.1 Hrs		136.3		5.63	5.68	06/08/96	03:12 PM	06/08/96	04:17 PM	61.0 L @ 100.0 CM/HR or 1.58 LPM
352	Wash	0.6	0.0	0.6 Hrs		137.1		5.68	5.71	06/08/96	04:17 PM	06/08/96	05:03 PM	61.0 L @ 50.0 CM/HR or 0.79 LPM
353	Elute A	0.8	0.0	0.8 Hrs		137.8		5.71	5.74	06/08/96	05:03 PM	06/08/96	05:49 PM	36.6 L @ 50.0 CM/HR or 0.79 LPM
354	Elute B	0.0	0.0	0.0 Hrs		137.8		5.74	5.74	06/08/96	05:49 PM	06/08/96	05:49 PM	36.6 L @ 50.0 CM/HR or 0.79 LPM
														0.0 L @ 30.0 CM/HR or 0.47 LPM

FIG. 12F

		Process Time Line													
		Duration (Hrs.)			Rel. Time Scale (Hrs.)			Acc. Days		Start		Finish			
	Operation	Calc.	A/D	Adj.	Prep	Exec.	Compl.	Start	End	Date	Time	Date	Time	Calculations	
						15.5				06/03/96	08:00 AM				
355	Regenerate	0.1	0.0	0.1 Hrs			138.0	5.74	5.75	06/08/96	05:49 PM	06/08/96	05:57 PM	12.2 L @ 100.0 CM/HR or 1.58 LPM	
356	Store	0.3	0.0	0.3 Hrs			138.2	5.75	5.76	06/08/96	05:57 PM	06/08/96	06:13 PM	24.4 L @ 100.0 CM/HR or 1.58 LPM	
357	CIP	1.0	0.0	1.0 Hrs			139.2	5.76	5.80	06/08/96	06:13 PM	06/08/96	07:13 PM		
358	SIP	1.0	0.0	1.0 Hrs			140.2	5.80	5.84	06/08/96	07:13 PM	06/08/96	08:13 PM		
359	Clean Up	1.0	0.0	1.0 Hrs			141.2	5.84	5.88	06/08/96	08:13 PM	06/08/96	09:13 PM		
360	Sub Total	6.7		6.7 Hrs		137.8								Max FR	1.58 LPM
361															
362	18 A Flow Dialysis														12.20 SF
363															
364	Set Up	1.0	0.0	1.0 Hrs	136.5			5.65	5.69	06/08/96	03:29 PM	06/08/96	04:29 PM		
365	Flush	0.7	0.0	0.7 Hrs	137.2			5.69	5.72	06/08/96	04:29 PM	06/08/96	05:09 PM	24.4 L @ 3.0 L/SF/Hr or 0.61 LPM	
366	Prime	0.7	0.0	0.7 Hrs	137.8			5.72	5.74	06/08/96	05:09 PM	06/08/96	05:49 PM	24.4 L @ 3.0 L/SF/Hr or 0.61 LPM	
367	Dialysis	1.0	0.0	1.0 Hrs		138.8		5.74	5.78	06/08/96	05:49 PM	06/08/96	06:49 PM	36.6 L @ 3.0 L/SF/Hr or 0.61 LPM	
368	Wash	0.0	0.0	0.0 Hrs		138.8		5.78	5.78	06/08/96	06:49 PM	06/08/96	06:49 PM	0.0 L @ 3.0 L/SF/Hr or 0.61 LPM	
369	Flush	0.3	0.0	0.3 Hrs			139.2	5.78	5.80	06/08/96	06:49 PM	06/08/96	07:09 PM	12.2 L @ 3.0 L/SF/Hr or 0.61 LPM	
370	Store	0.7	0.0	0.7 Hrs			139.8	5.80	5.83	06/08/96	07:09 PM	06/08/96	07:49 PM	24.4 L @ 3.0 L/SF/Hr or 0.61 LPM	
371	CIP	1.0	0.0	1.0 Hrs			140.8	5.83	5.87	06/08/96	07:49 PM	06/08/96	08:49 PM		
372	SIP	1.0	0.0	1.0 Hrs			141.8	5.87	5.91	06/08/96	08:49 PM	06/08/96	09:49 PM		
373	Clean Up	1.0	0.0	1.0 Hrs			142.8	5.91	5.95	06/08/96	09:49 PM	06/08/96	10:49 PM		
374	Sub Total	7.3		7.3 Hrs		138.8								Max FR	0.61 LPM
375															
376	19 A P/A MPLC													7.0 L CV 0.4 H/D	28.81 CM Dia.
377															
378	Equilibration	0.5	0.0	0.5 Hrs	138.5			5.75	5.77	06/08/96	05:59 PM	06/08/96	06:31 PM	34.8 L @ 100.0 CM/HR	1.09 LPM
379	Load	0.2	0.0	0.2 Hrs		139.1		5.78	5.79	06/08/96	06:49 PM	06/08/96	07:03 PM	7.3 L @ 50.0 CM/HR	0.54 LPM
380	Wash	0.6	0.0	0.6 Hrs		139.7		5.79	5.82	06/08/96	07:03 PM	06/08/96	07:41 PM	20.9 L @ 50.0 CM/HR	0.54 LPM
381	Elute A	0.6	0.0	0.6 Hrs		140.3		5.82	5.85	06/08/96	07:41 PM	06/08/96	08:20 PM	20.9 L @ 50.0 CM/HR	0.54 LPM
382	Elute B	0.0	0.0	0.0 Hrs		140.3		5.85	5.85	06/08/96	08:20 PM	06/08/96	08:20 PM	0.0 L @ 30.0 CM/HR	0.33 LPM
383	Regenerate	0.1	0.0	0.1 Hrs			140.4	5.85	5.85	06/08/96	08:20 PM	06/08/96	08:26 PM	7.0 L @ 100.0 CM/HR	1.09 LPM
384	Store	0.2	0.0	0.2 Hrs			140.7	5.85	5.86	06/08/96	08:26 PM	06/08/96	08:39 PM	13.9 L @ 100.0 CM/HR	1.09 LPM
385	CIP	1.0	0.0	1.0 Hrs			141.7	5.86	5.90	06/08/96	08:39 PM	06/08/96	09:39 PM		
386	SIP	1.0	0.0	1.0 Hrs			142.7	5.90	5.94	06/08/96	09:39 PM	06/08/96	10:39 PM		
387	Clean Up	1.0	0.0	1.0 Hrs			143.7	5.94	5.99	06/08/96	10:39 PM	06/08/96	11:39 PM		
388	Sub Total	5.4		5.4 Hrs		140.3								Max FR	1.09 LPM
389															
390	20 A Flow Dialysis														2.43 SF
391															
392	Set Up	0.0	0.0	0.0 Hrs	139.0			5.79	5.79	06/08/96	07:00 PM	06/08/96	07:00 PM		
393	Flush	0.7	0.0	0.7 Hrs	139.7			5.79	5.82	06/08/96	07:00 PM	06/08/96	07:40 PM	4.9 L @ 3.0 L/SF/Hr or 0.12 LPM	
394	Prime	0.7	0.0	0.7 Hrs	140.3			5.82	5.85	06/08/96	07:40 PM	06/08/96	08:20 PM	4.9 L @ 3.0 L/SF/Hr or 0.12 LPM	
395	Dialysis	2.0	0.0	2.0 Hrs		142.3		5.85	5.93	06/08/96	08:20 PM	06/08/96	10:20 PM	14.6 L @ 3.0 L/SF/Hr or 0.12 LPM	
396	Wash	0.0	0.0	0.0 Hrs		142.3		5.93	5.93	06/08/96	10:20 PM	06/08/96	10:20 PM	0.0 L @ 3.0 L/SF/Hr or 0.12 LPM	
397	Flush	0.3	0.0	0.3 Hrs			142.7	5.93	5.94	06/08/96	10:20 PM	06/08/96	10:40 PM	2.4 L @ 3.0 L/SF/Hr or 0.12 LPM	
398	Store	0.7	0.0	0.7 Hrs			143.3	5.94	5.97	06/08/96	10:40 PM	06/08/96	11:20 PM	4.9 L @ 3.0 L/SF/Hr or 0.12 LPM	
399	CIP	0.0	0.0	0.0 Hrs			143.3	5.97	5.97	06/08/96	11:20 PM	06/08/96	11:20 PM		
400	SIP	0.0	0.0	0.0 Hrs			143.3	5.97	5.97	06/08/96	11:20 PM	06/08/96	11:20 PM		
401	Clean Up	0.0	1.0	1.0 Hrs			144.3	5.97	6.01	06/08/96	11:20 PM	06/09/96	12:20 AM		
402	Sub Total	4.3		5.3 Hrs		142.3								Max FR	0.12 LPM
403															
404	21 A P/A MPLC													5.3 L CV 0.4 H/D	26.35 CM Dia.
405															
406	Equilibration	0.5	0.0	0.5 Hrs	142.0			5.89	5.91	06/08/96	09:28 PM	06/08/96	09:57 PM	26.6 L @ 100.0 CM/HR	0.91 LPM
407	Load	0.1	0.0	0.1 Hrs		142.4		5.93	5.94	06/08/96	10:20 PM	06/08/96	10:26 PM	2.9 L @ 50.0 CM/HR	0.45 LPM
408	Wash	0.6	0.0	0.6 Hrs		143.0		5.94	5.98	06/08/96	10:26 PM	06/08/96	11:01 PM	16.0 L @ 50.0 CM/HR	0.45 LPM
409	Elute A	0.6	0.0	0.6 Hrs		143.6		5.98	5.98	06/08/96	11:01 PM	06/08/96	11:36 PM	16.0 L @ 50.0 CM/HR	0.45 LPM
410	Elute B	0.0	0.0	0.0 Hrs		143.6		5.98	5.98	06/08/96	11:36 PM	06/08/96	11:36 PM	0.0 L @ 30.0 CM/HR	0.27 LPM
411	Regenerate	0.1	0.0	0.1 Hrs			143.7	5.98	5.99	06/08/96	11:36 PM	06/08/96	11:42 PM	5.3 L @ 100.0 CM/HR	0.91 LPM
412	Store	0.2	0.0	0.2 Hrs			143.9	5.99	6.00	06/08/96	11:42 PM	06/08/96	11:54 PM	10.6 L @ 100.0 CM/HR	0.91 LPM
413	CIP	0.0	0.0	0.0 Hrs			143.9	6.00	6.00	06/08/96	11:54 PM	06/08/96	11:54 PM		
414	SIP	0.0	0.0	0.0 Hrs			143.9	6.00	6.00	06/08/96	11:54 PM	06/08/96	11:54 PM		

FIG. 12G

	Operation	Duration (Hrs.) Calc.	A/D	Adj.	Rel. Time Scale (Hrs) Prep	Exec.	Compl.	Abs. Days Start	End	Start Date	Start Time	Finish Date	Finish Time	Calculations
415						15.5				06/03/96	08:00 AM			
416	Clean Up	1.0	0.0	1.0 Hrs			144.9	6.00	6.04	06/08/96	11:54 PM	06/09/96	12:54 AM	
417	Sub Total	2.1		2.1 Hrs		143.6								Max FR 0.91 LPM
418	22 A Sterile Filtration													
419														0.09 SF
420	Set Up	0.5	0.0	[illegible]	152.6			6.34	6.36	06/09/96	08:06 AM	06/09/96	08:36 AM	
421	Filtration	0.5	0.0	0.5 Hrs		144.1		5.98	6.00	06/08/96	11:36 PM	06/09/96	12:06 AM	2.2 L @ 50.0 L/SF/Hr or 0.07 LPM
422	Storage	0.5	0.0	0.5 Hrs			144.6	6.00	6.03	06/09/96	12:06 AM	06/09/96	12:36 AM	
423	CIP	0.0	0.0	0.0 Hrs			144.6	6.03	6.03	06/09/96	12:36 AM	06/09/96	12:36 AM	
424	SIP	0.0	0.0	0.0 Hrs			144.6	6.03	6.03	06/09/96	12:36 AM	06/09/96	12:36 AM	
425	Clean Up	1.0	0.0	1.0 Hrs			145.6	6.03	6.07	06/09/96	12:36 AM	06/09/96	01:36 AM	
426	Sub Total	1.5		1.5 Hrs		144.1								Max FR 0.07 LPM

FIG. 12H

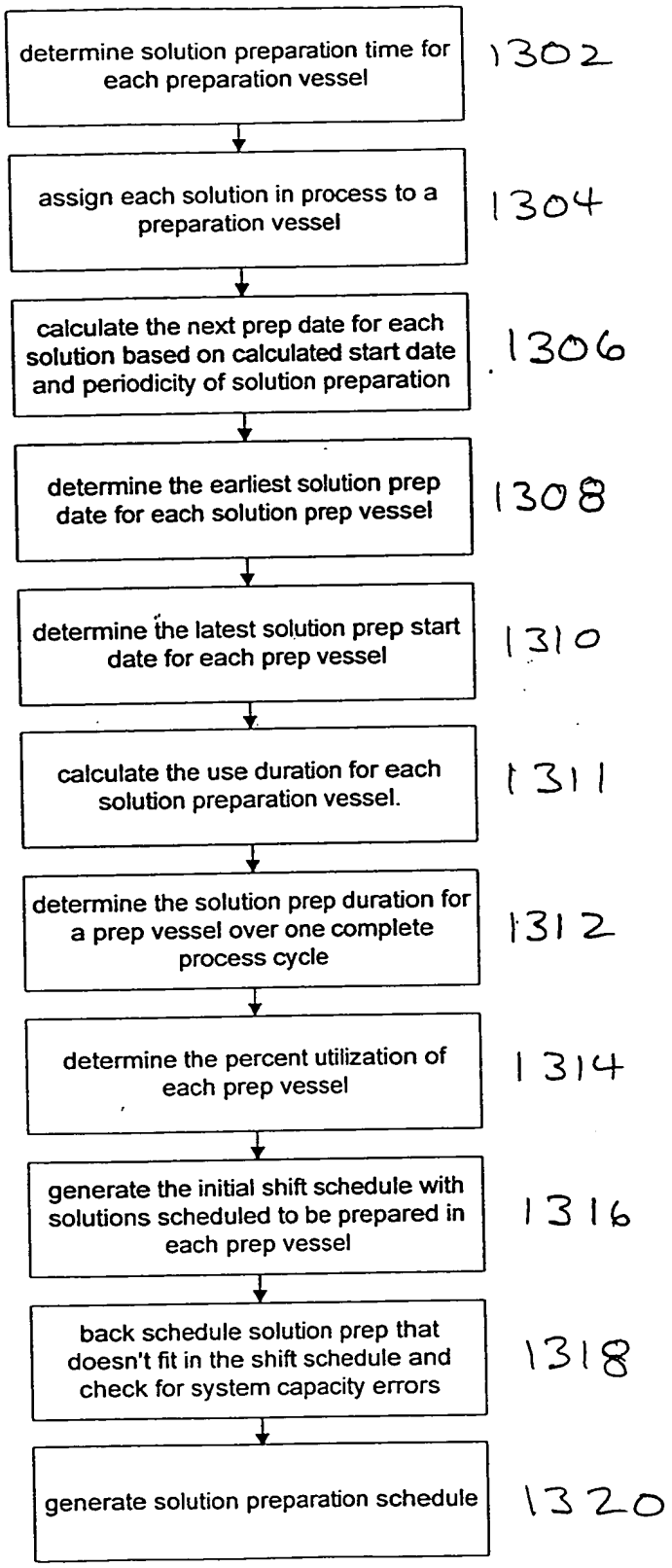

determine solution preparation time for each preparation vessel
1302
assign each solution in process to a preparation vessel
1304
calculate the next prep date for each solution based on calculated start date and periodicity of solution preparation
1306
determine the earliest solution prep date for each solution prep vessel
1308
determine the latest solution prep start date for each prep vessel
1310
calculate the use duration for each solution preparation vessel.
1311
determine the solution prep duration for a prep vessel over one complete process cycle
1312
determine the percent utilization of each prep vessel
1314
generate the initial shift schedule with solutions scheduled to be prepared in each prep vessel
1316
back schedule solution prep that doesn't fit in the shift schedule and check for system capacity errors
1318
generate solution preparation schedule
1320

FIG. 13

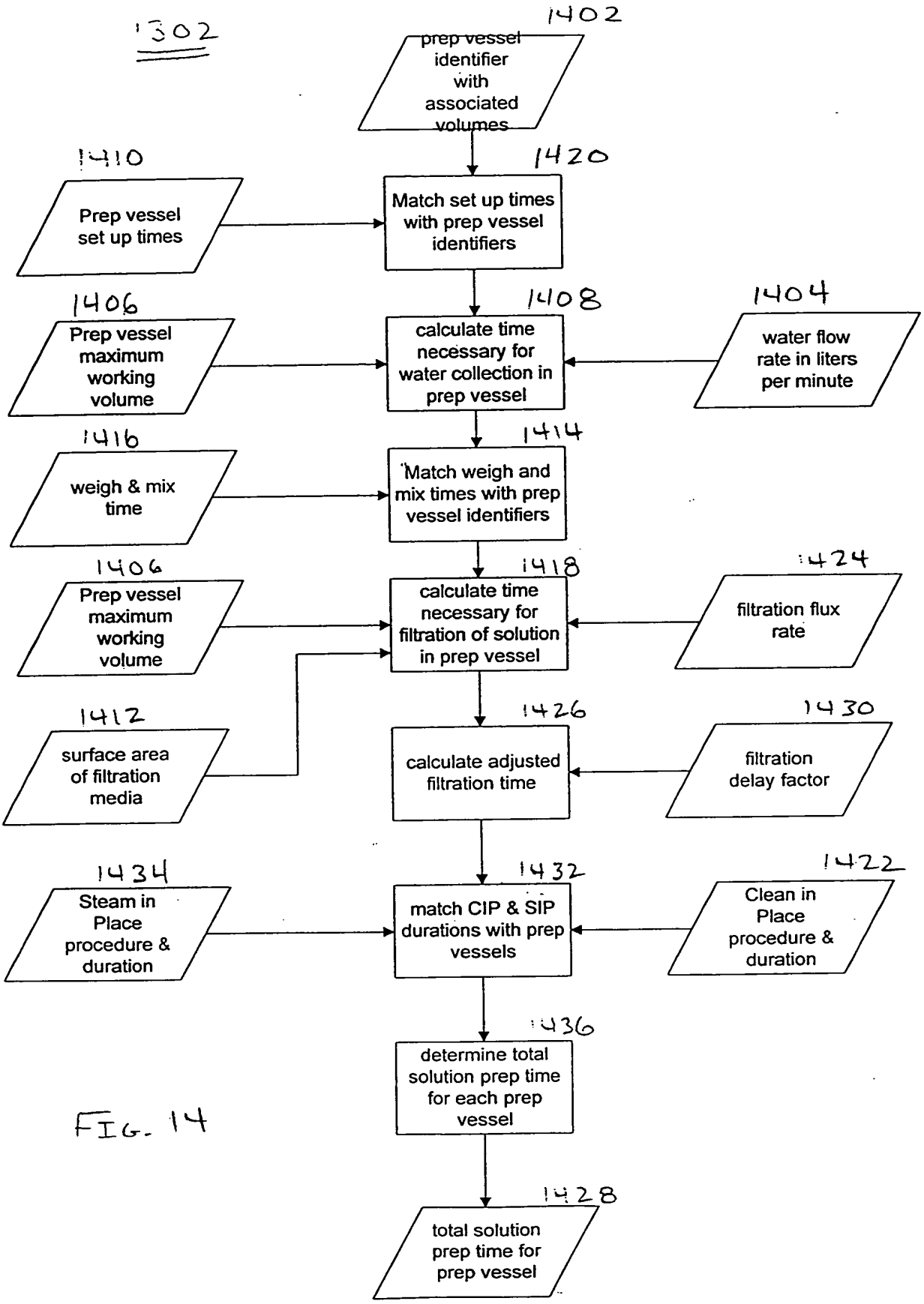

1302
1402
prep vessel identifier with associated volumes
1410
Prep vessel set up times
1420
Match set up times with prep vessel identifiers
1406
Prep vessel maximum working volume
1408
calculate time necessary for water collection in prep vessel
1404
water flow rate in liters per minute
1416
weigh & mix time
1414
Match weigh and mix times with prep vessel identifiers
1406
Prep vessel maximum working volume
1418
calculate time necessary for filtration of solution in prep vessel
1424
filtration flux rate
1412
surface area of filtration media
1426
calculate adjusted filtration time
1430
filtration delay factor
1434
Steam in Place procedure & duration
1432
match CIP & SIP durations with prep vessels
1422
Clean in Place procedure & duration
1436
determine total solution prep time for each prep vessel
1428
total solution prep time for prep vessel

FIG. 14

Solution Prep Vessel List/Procedure

Batch Tank		Batch Tank			Set Up Min.	Water Collect.		Weigh/ Mix Min.	Ultrafiltration/Microfiltration					CIP			Total		Perc. Util.
No.	Min. LWV	No.	Min. LWV	Max. LWV		LPM	Min.		SF	L/SF/HR	Min.	Delay Factor	Adj. Min.	Cycle	Min.	SIP	Min.	Hrs.	
101	0.5	101	0.5	1	10		1	15	0.5	25	4.8	1.2	5.76				31.76	0.5	
102	1	102	1	2	10		1	15	1	25	4.8	1.2	5.76				31.76	0.5	2%
103	2	103	2	4	20		2	30	1	25	9.6	1.2	11.52				63.52	1.1	
104	4	104	4	10	20	10	1	30	2	25	12	1.2	14.4				65.4	1.1	4%
105	10	105	10	20	20	10	2	30	2	25	24	1.2	28.8				80.8	1.3	
106	20	106	20	50	20	10	5	30	10	25	12	1.2	14.4	CIP-1	60	40	109.4	1.8	3%
107	50	107	50	100	20	10	10	30	10	25	24	1.2	28.8	CIP-1	60	40	128.8	2.1	8%
108	100	108	100	250	0.5	50	5	30	30	25	20	1.2	24	CIP-1	60	40	99.5	1.7	18%
109	250	109	250	500	0.5	50	10	30	30	25	40	1.2	48	CIP-1	60	40	128.5	2.1	11%
110	500	110	500	1,500	1	50	30	30	60	25	60	1.2	72	CIP-1	60	40	173	2.9	10%
111	1500	111	1500	3,000	1	50	60	30	60	25	120	1.2	144	CIP-1	60	40	275	4.6	16%

1402 1406 1410 1404 1502 1410 1412 1424 1506 1422 1434 1428

FIG. 15

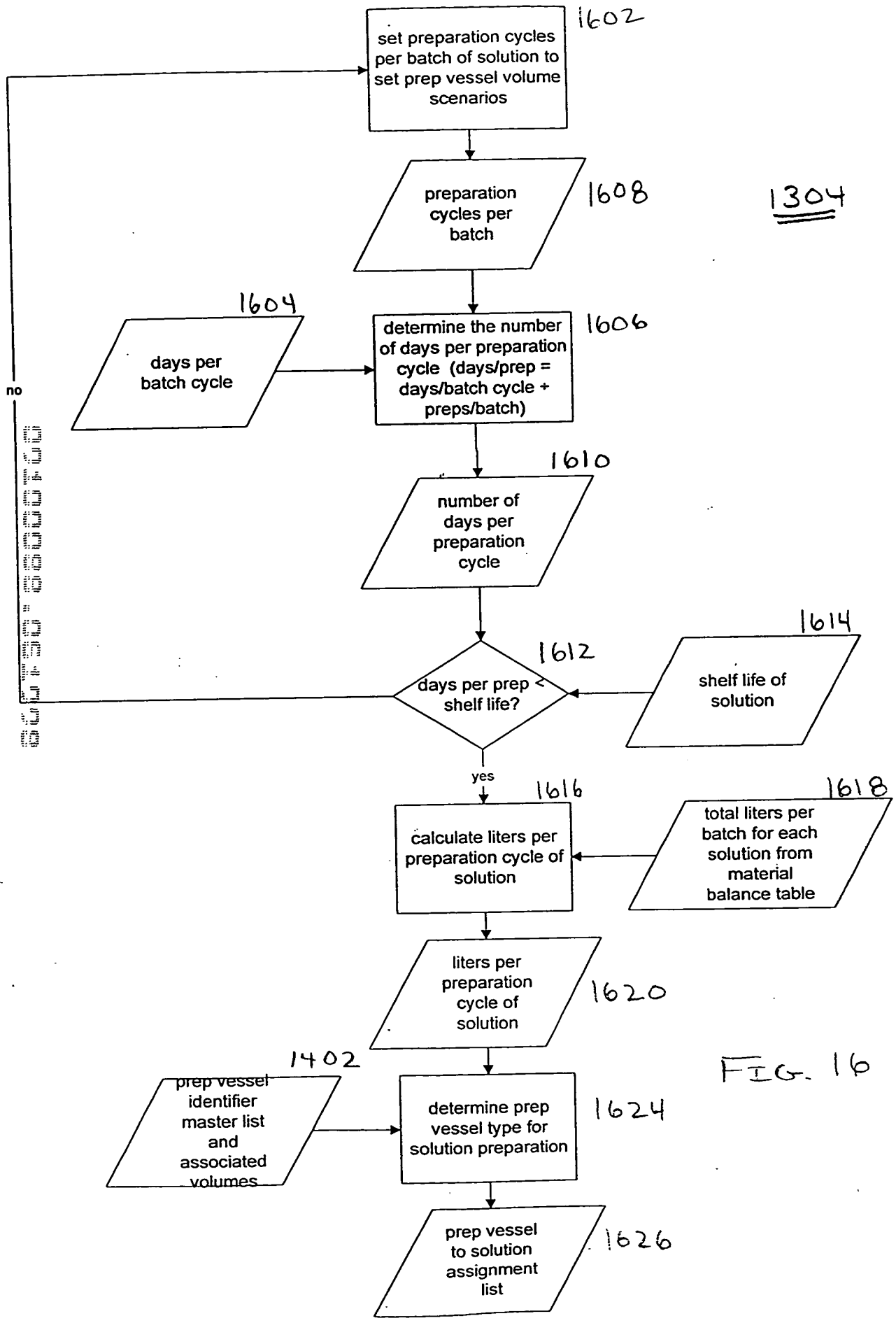

set preparation cycles per batch of solution to set prep vessel volume scenarios
1602
preparation cycles per batch
1608
1304
1604
days per batch cycle
determine the number of days per preparation cycle (days/prep = days/batch cycle ÷ preps/batch)
1606
no
1610
number of days per preparation cycle
1614
1612
days per prep < shelf life?
shelf life of solution
yes
1616
1618
calculate liters per preparation cycle of solution
total liters per batch for each solution from material balance table
liters per preparation cycle of solution
1620
1402
prep vessel identifier master list and associated volumes
determine prep vessel type for solution preparation
1624
prep vessel to solution assignment list
1626

FIG. 16

Solution Prep Campaign Format

1626

	Soln. ID	Storage Cond. RT	4C	XP	Soln. Prep Format MOD	BOD	BIA	Solution Prep Cycles Liters/ Batch	Preps/ Batch	Liters/ Prep	Days/ Bat. Cy.	Days/ Prep	Shelf Days	Shelf Check	101 0.6 1	102 1 2	103 2 4	104 4 10	105 10 20	106 20 50	107 50 100
1	S-0101	X			0	x	0	1,666.50	1	1,666.50	7	7	56	OK		102					
2	S-0102	X			0	x	0	1.65	1	1.65	7	7	180	OK		102					
3	S-0103	X			0	x	0	1.65	1	1.65	7	7	56	OK				104			
4	S-0104	X			0	x	0	8.25	1	8.25	7	7	56	OK				104			
5	S-0105	X			0	x	0	8.25	1	8.25	7	7	56	OK							
6	S-0106	X			0	x	0	560.61	1	560.61	7	7	56	OK							
7	S-0107	X			0	x	0	125.93	1	125.93	7	7	56	OK							
8	S-0108	X			0	x	0	177.41	1	177.41	7	7	56	OK						106	
9	S-0109	X			0	x	0	22.18	1	22.18	7	7	56	OK							107
10	S-0111	X			0	x	0	56.52	1	56.52	7	7	56	OK							
11	S-0112	X			0	x	0	113.03	1	113.03	7	7	56	OK							
12	S-0113	X			0	x	0	1,612.45	1	1,612.45	7	7	56	OK							
13	S-0114	X			0	x	0	574.10	1	574.10	7	7	56	OK							
14	S-0115	X			0	x	0	248.83	1	248.83	7	7	56	OK							
15	S-0116	X			0	x	0	497.65	1	497.65	7	7	56	OK							
16	S-0117	X			0	x	0	109.80	1	109.80	7	7	56	OK							
17	S-0118	X			0	x	0	497.65	1	497.65	7	7	56	OK							
18	S-0119	X			0	x	0	292.79	1	292.79	7	7	56	OK							
19	S-0120	X			0	x	0	109.80	1	109.80	7	7	56	OK		1710		1714		1718	107
20	S-0121	X			0	x	0	62.58	1	62.58	7	7	56	OK							
21	S-0122	x			0	x	0	0.00	1	0.00	7	7	56	OK	1708		1712		1716		1720

1704 1618 1608 1620 1604 1610 1614 1706

Fig. 17

1626

Solution Prep Campaign Format

SCREEN SHOWING

	Soln. ID	108 100 250	109 250 500	110 500 1500	111 1500 3000	Tank Assignment Initial Assign.	Tank Assignment Final Assign.	Solution Prep Schedule Required By	Back Days	Avail. By	Hold Days	Init. Start	Float Days	Final Start	Next Prep	Prep. Hrs.	Tank Fi 101
1	S-0101				111	111	111	06/03/96	1	05/31/96	2	05/29/96	0	05/29/96	06/05/96	4	
2	S-0102					102	102	06/05/96	1	06/04/96	2	05/31/96	0	05/31/96	06/07/96	4	
3	S-0103					102	102	06/05/96	1	06/04/96	2	05/31/96	0	05/31/96	06/07/96	4	
4	S-0104					104	104	06/05/96	1	06/04/96	2	05/31/96	0	05/31/96	06/07/96	4	
5	S-0105					104	104	06/05/96	1	06/04/96	2	05/31/96	0	05/31/96	06/07/96	4	
6	S-0106			110		110	110	06/07/96	1	06/06/96	2	06/04/96	0	06/04/96	06/11/96	4	
7	S-0107	108				108	108	06/11/96	1	06/10/96	2	06/07/96	0	06/07/96	06/14/96	4	
8	S-0108	108				108	108	06/11/96	1	06/10/96	2	06/07/96	0	06/07/96	06/14/96	4	
9	S-0109					106	106	06/12/96	1	06/11/96	2	06/07/96	0	06/07/96	06/14/96	4	
10	S-0111					107	107	06/12/96	1	06/11/96	2	06/07/96	0	06/07/96	06/14/96	4	
11	S-0112	108				108	108	06/12/96	1	06/11/96	2	06/07/96	0	06/07/96	06/14/96	4	
12	S-0113				111	111	111	06/12/96	1	06/11/96	2	06/07/96	0	06/07/96	06/14/96	4	
13	S-0114			110		110	110	06/12/96	1	06/11/96	2	06/07/96	0	06/07/96	06/14/96	4	
14	S-0115	108				108	108	06/12/96	1	06/11/96	2	06/07/96	0	06/07/96	06/14/96	4	
15	S-0116		109			109	109	06/12/96	1	06/11/96	2	06/07/96	0	06/07/96	06/14/96	4	
16	S-0117	108				108	108	06/12/96	1	06/11/96	2	06/07/96	0	06/07/96	06/14/96	4	
17	S-0118		109			109	109	06/12/96	1	06/11/96	2	06/07/96	0	06/07/96	06/14/96	4	
18	S-0119		109			109	109	06/12/96	1	06/11/96	2	06/07/96	0	06/07/96	06/14/96	4	
19	S-0120	108				108	108	06/12/96	1	06/11/96	2	06/07/96	0	06/07/96	06/14/96	4	
20	S-0121					107	107	06/12/96	1	06/11/96	2	06/07/96	0	06/07/96	06/14/96	4	
21	S-0122					0	0	06/12/96	1	06/11/96	2	06/07/96	0	06/07/96	06/14/96	4	

1722 1724 1726 1728

Min	06/03/96
Max	06/12/96
Sat	0
Sun	0

Min. 05/29/96 06/14/96
Min

FIG 18

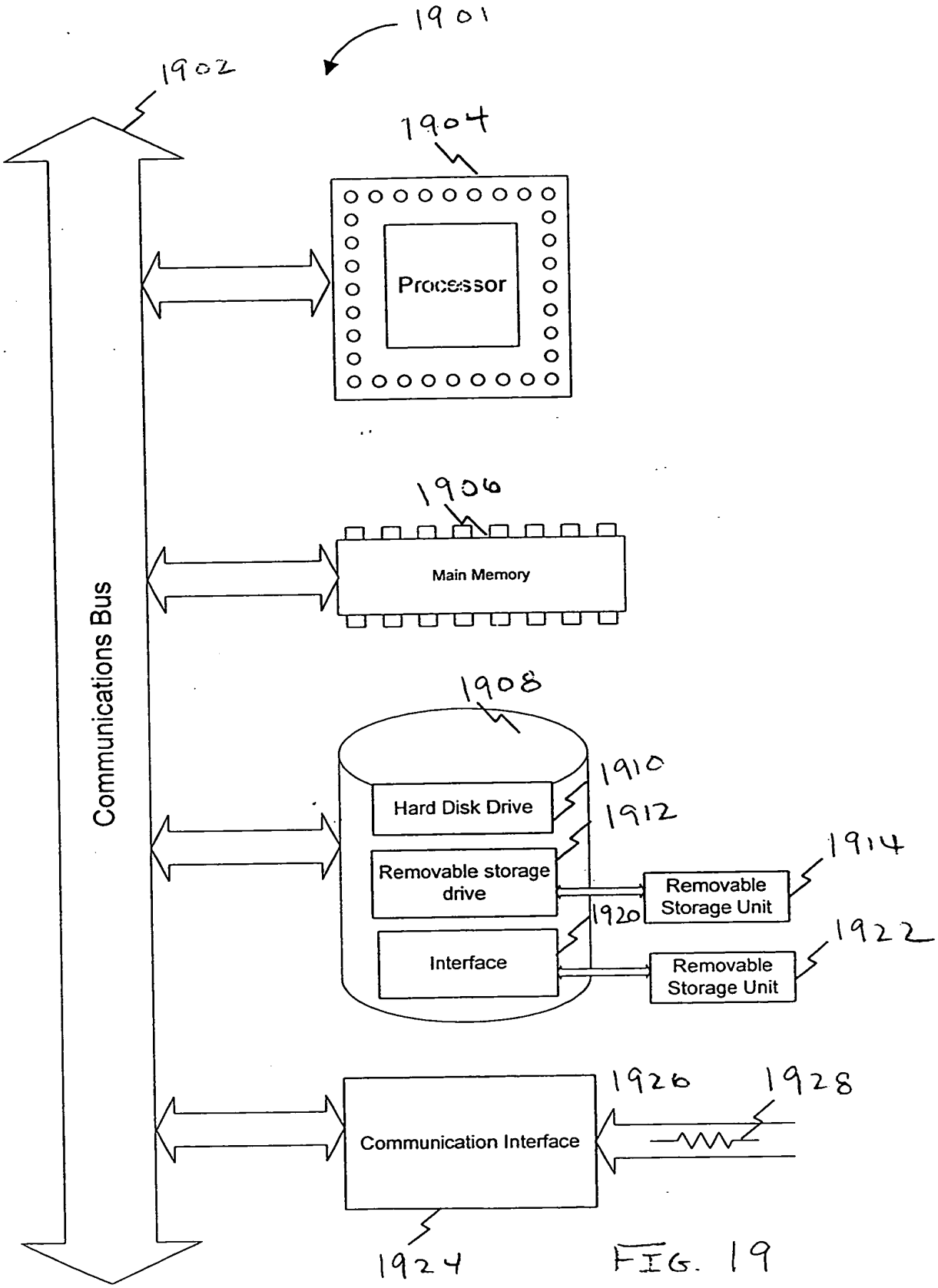

1901
1902
1904
Processor
1906
Main Memory
1908
1910
Hard Disk Drive
1912
Removable storage drive
1914
Removable Storage Unit
1920
Interface
1922
Removable Storage Unit
Communications Bus
1926
1928
Communication Interface
1924

FIG. 19

1306

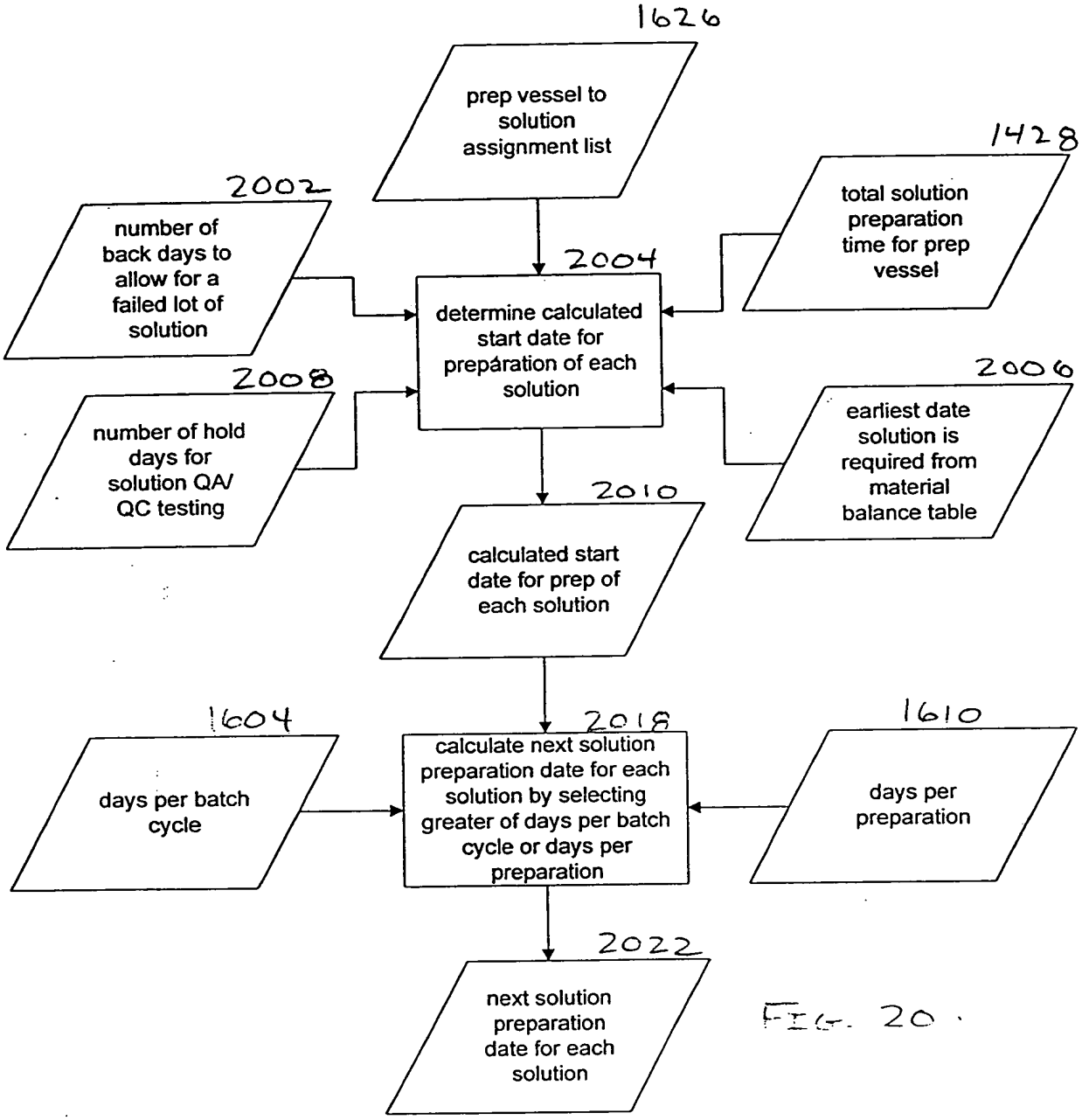

1626
prep vessel to solution assignment list
1428
total solution preparation time for prep vessel
2002
number of back days to allow for a failed lot of solution
2004
determine calculated start date for preparation of each solution
2008
number of hold days for solution QA/ QC testing
2006
earliest date solution is required from material balance table
2010
calculated start date for prep of each solution
1604
days per batch cycle
2018
calculate next solution preparation date for each solution by selecting greater of days per batch cycle or days per preparation
1610
days per preparation
2022
next solution preparation date for each solution

FIG. 20

2102 2104 2106

	Category/Assay	Code	Man Hour			Disp. Material
			Set Up	Per Sample	Clean Up	
1	Environmental					
2	Temperature	E-1	0.5	0.1	0.5	
3	Humidity	E-2	0.5	0.1	0.5	
4	Particle Count	E-3	0.5	0.2	0.5	
5						
6	Analytical					
7	Visual					
8	Certificate of Analysis	AV-1	0.25	0.2	0.5	
9	Appearance	AV-2	0.25	0.05	0.25	
10	Chemical					
11	Solubility	AC-1	0.5	0.1	0.5	
12	pH	AC-2	0.25	0.05	0.25	
13	Osmolality	AC-3	0.25	0.1	0.25	
14	Water Content (by Karl Fischer)	AC-4	0.5	0.2	0.5	
15	Key Element Analysis (by ICP Atomic Adsorbtion Spectroscopy)	AC-5	1	0.25	1	
16	GC/Mass Spec	AC-6	1	0.25	1	
17	Biochemical					
18	DNA					
19	DNA Fluorochrome Stain	AB-1	0.5	0.1	0.5	
20	Protein					
21	Hemoglobin	AB-2	0.5	0.1	0.5	
22	Electrophoretic Profiles by SDS-PAGE	AB-3	1	0.2	1	
23	A280	AB-4	0.25	0.1	0.25	
24	Bradford Assay	AB-5	0.5	0.1	0.5	
25	Amino Acid Analysis by HPLC	AB-6	1	0.25	1	
26	Endotoxin		0.5	0.1	0.5	
27	Gel Clot LAL	AB-7				
28	Immunological					
29	ELISA	AI-1	1	0.1	1	
30	Western Blots	AI-2	1.5	0.2	1.5	
31	Activity					
32	Chromagenic Substrate Assays	AA-1	1	0.1	1	
33						
34	In Vitro Biological					
35	Microbilogical	VB-1	0.5	0.2	0.5	
36	Mycoplasma (Barile Method)	VB-2	0.5	0.2	0.5	
37	Bacteriophage (Screened)	VB-3	0.5	0.2	0.5	
38	Cell Passage Test	VB-4	1	0.2	1	
39	Adventitious viral Agents		2	0.2	1	
40	CPE	VB-5	2	0.2	1	
41	BVD	VB-6	2	0.2	1	
42	P13	VB-7	2	0.2	1	
43	IBR	VB-8	2	0.2	1	
44	Virus Neutralization Titers (9CFR)					
45	BVD	VB-9	2	0.2	1	
46	P13	VB-10	2	0.2	1	
47	IBR	VB-11	2	0.2	1	
48	Tritiated Thymidine Uptake in Mouse Cells	VB-12	2	0.2	1	
49	General Safety Test (Guinea Pigs)	VB-13	1	0.2	1	
50						
51						

FIG. 21

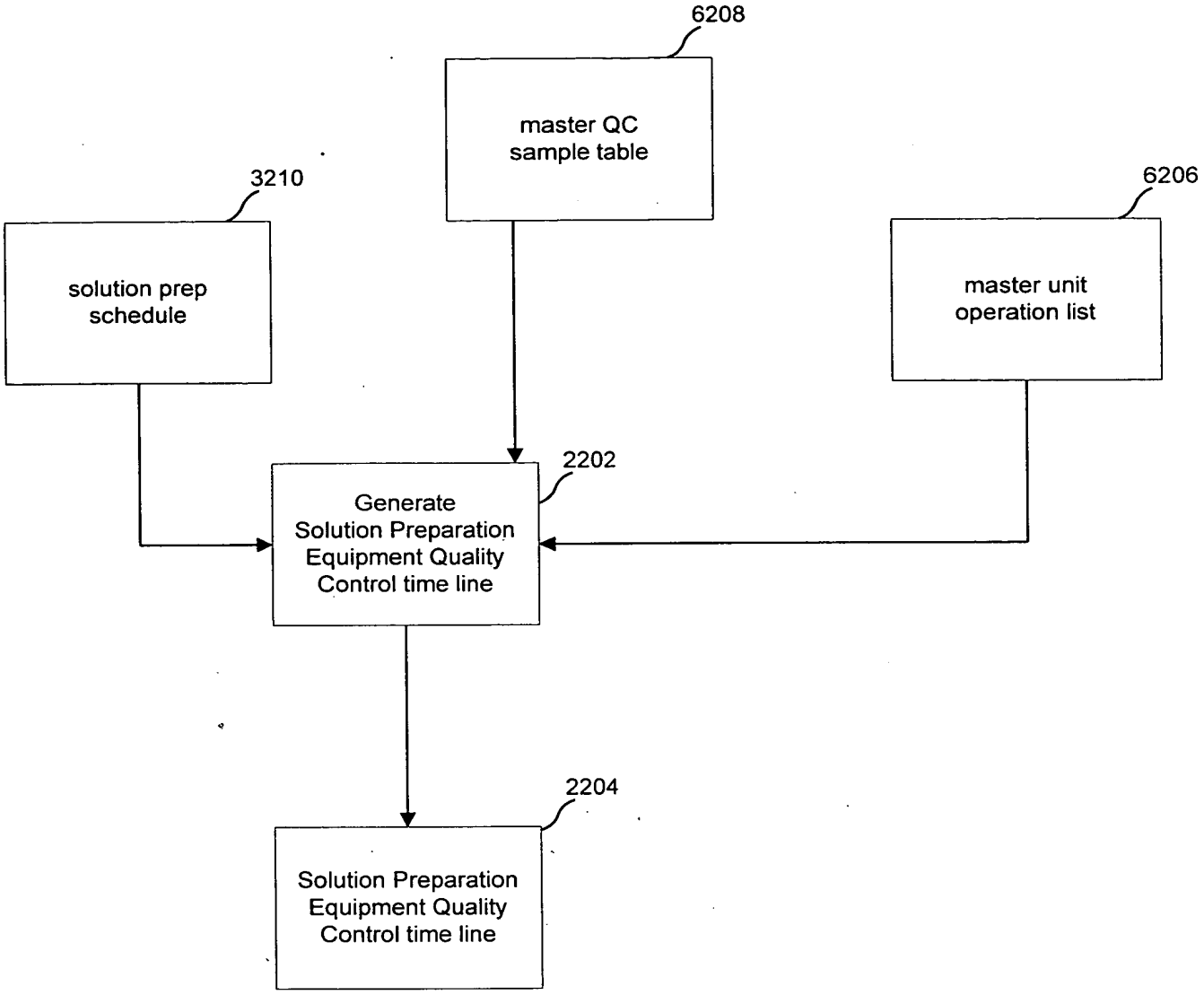


FIG. 22

9805-12.vsd/1

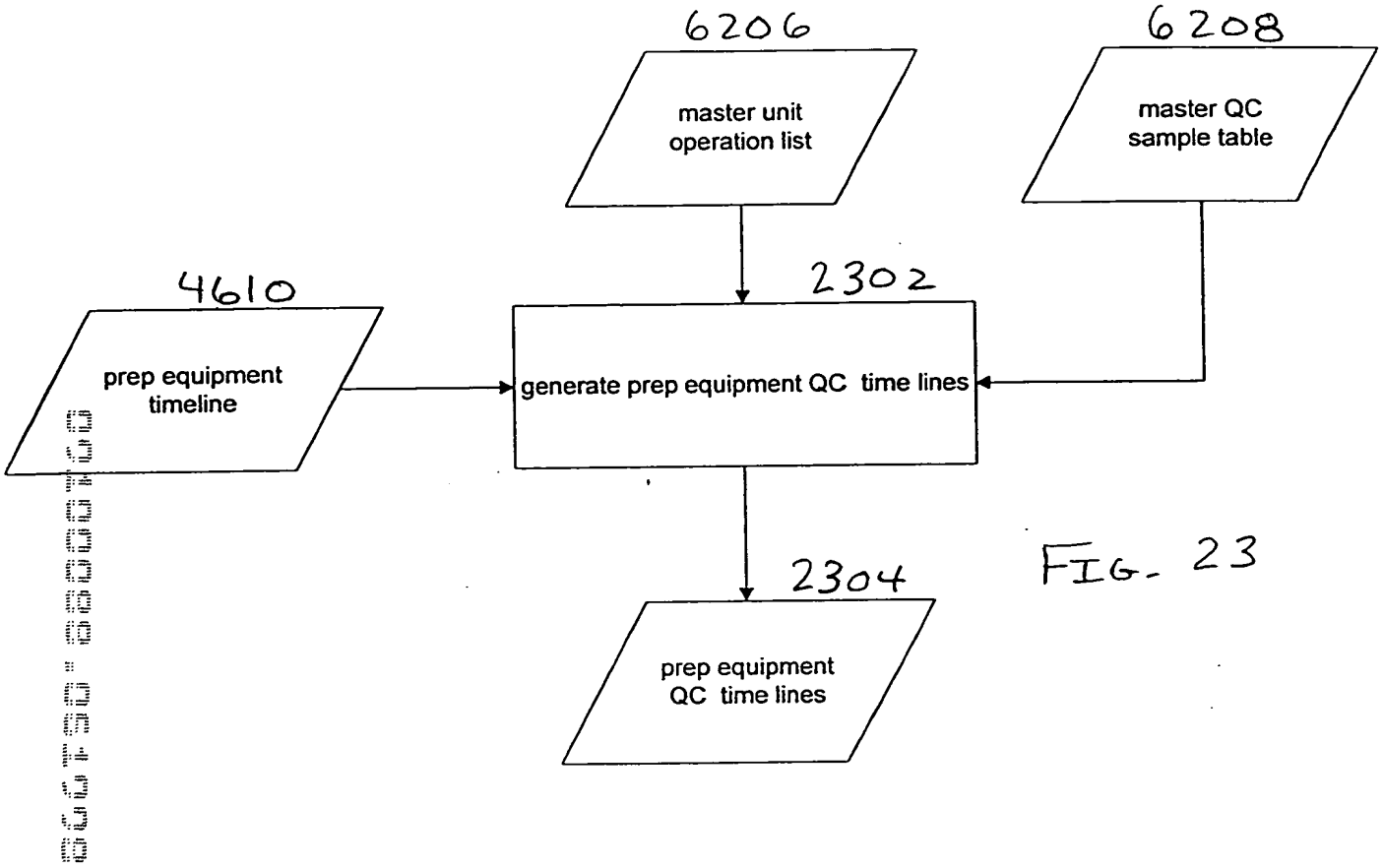

6206
master unit operation list
6208
master QC sample table
4610
prep equipment timeline
2302
generate prep equipment QC time lines
2304
prep equipment QC time lines

FIG. 23

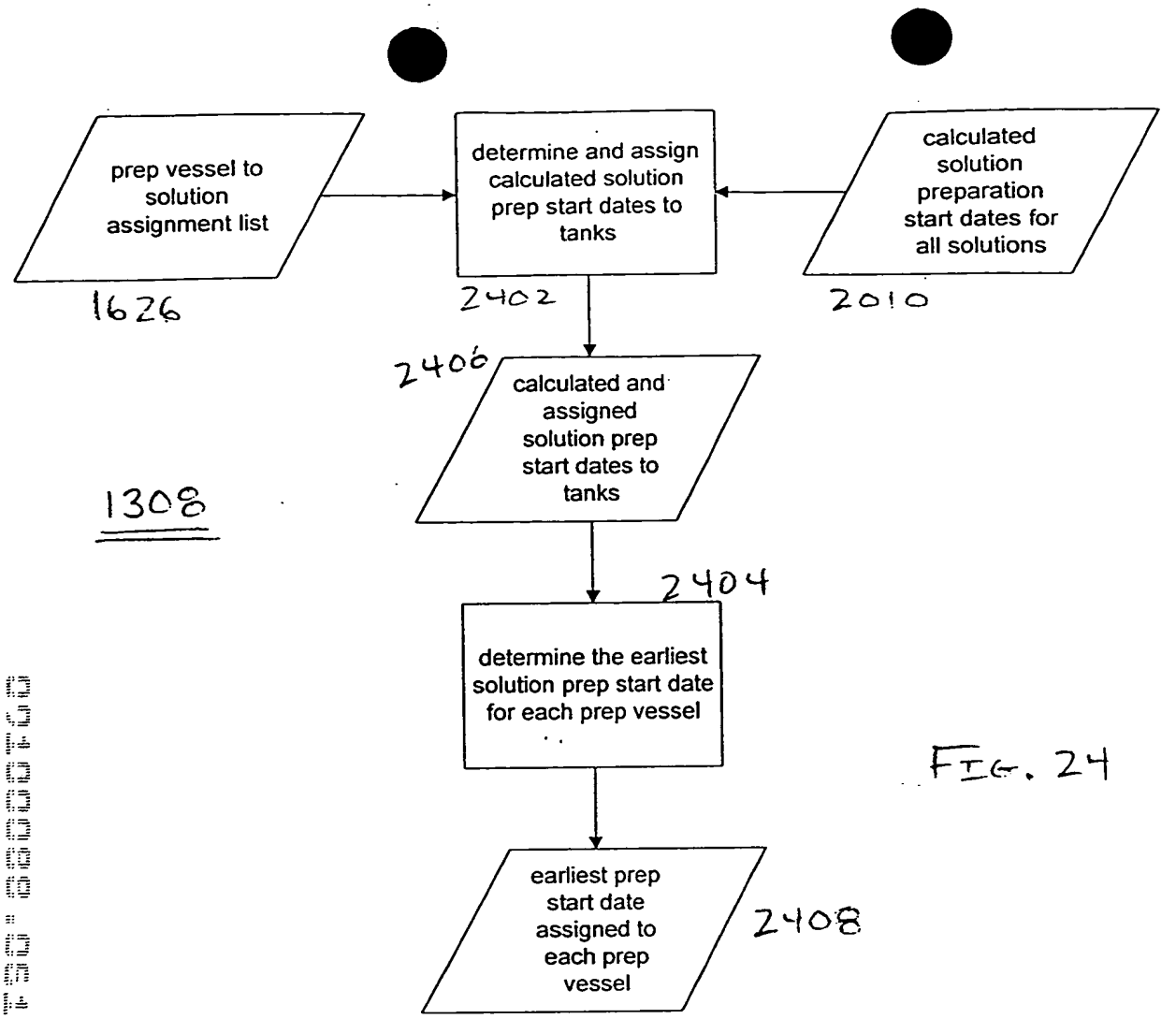

prep vessel to solution assignment list
1626
determine and assign calculated solution prep start dates to tanks
2402
calculated solution preparation start dates for all solutions
2010
2406
calculated and assigned solution prep start dates to tanks
1308
2404
determine the earliest solution prep start date for each prep vessel
earliest prep start date assigned to each prep vessel
2408

FIG. 24

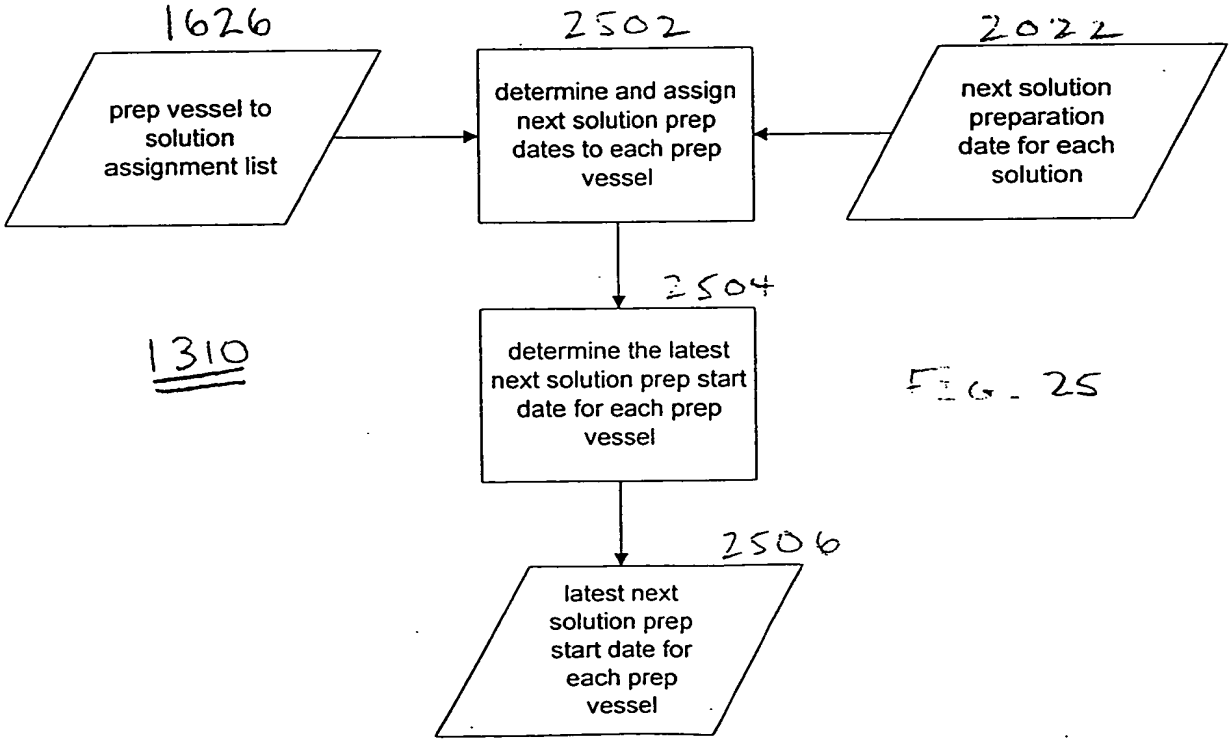

1626
prep vessel to solution assignment list
2502
determine and assign next solution prep dates to each prep vessel
2022
next solution preparation date for each solution
2504
1310
determine the latest next solution prep start date for each prep vessel
2506
latest next solution prep start date for each prep vessel

FIG. 25

1312

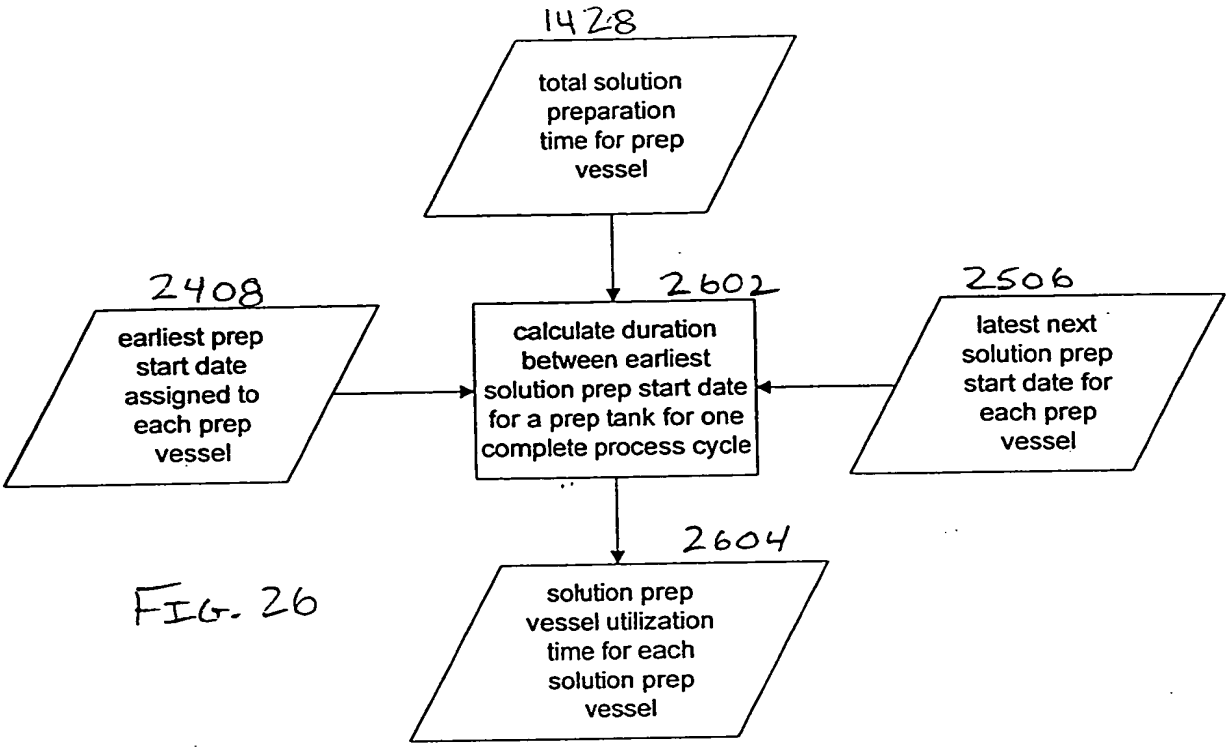

1428
total solution preparation time for prep vessel
2408
earliest prep start date assigned to each prep vessel
2602
calculate duration between earliest solution prep start date for a prep tank for one complete process cycle
2506
latest next solution prep start date for each prep vessel
2604
solution prep vessel utilization time for each solution prep vessel

FIG. 26

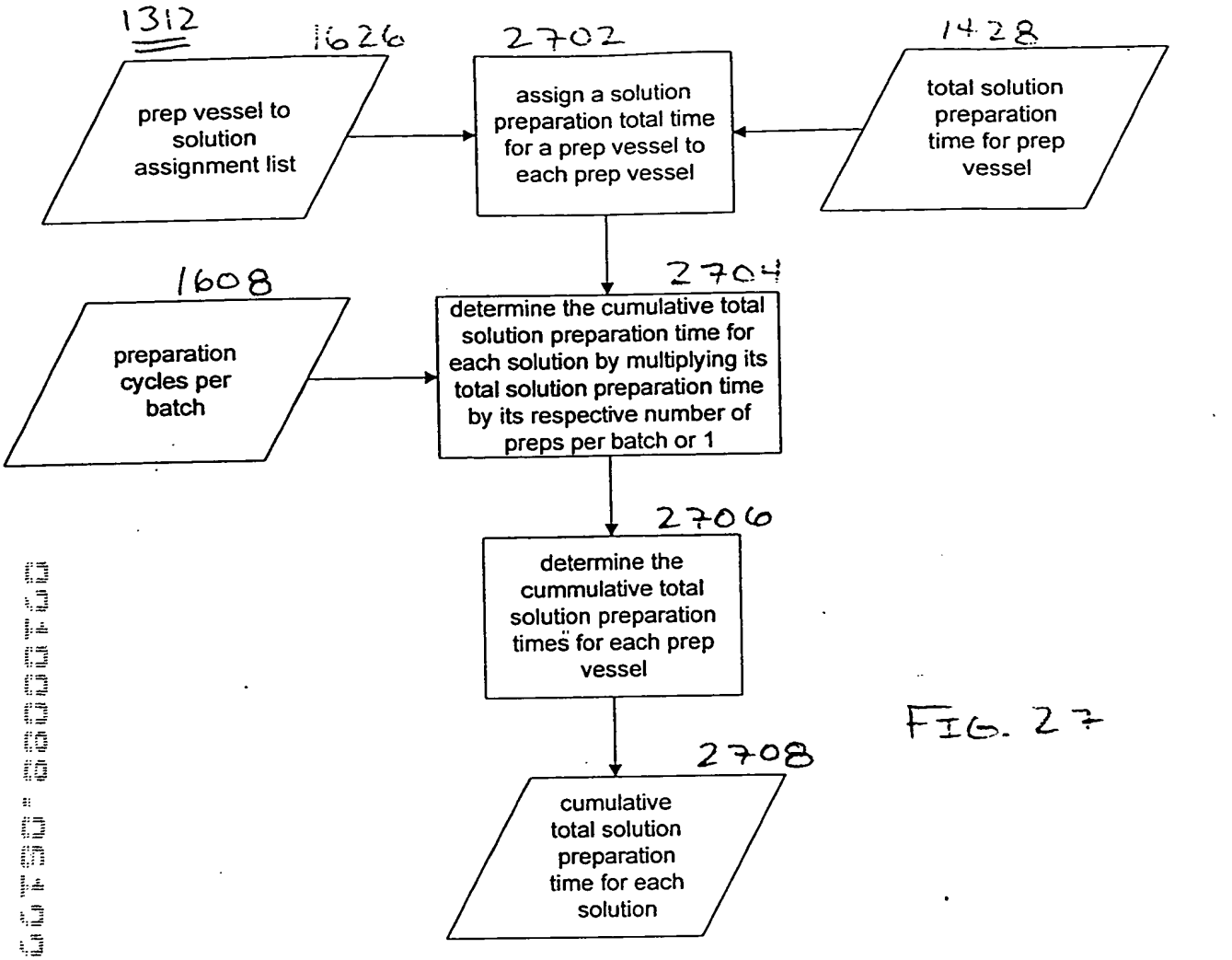

1312
1626
prep vessel to solution assignment list
2702
assign a solution preparation total time for a prep vessel to each prep vessel
1428
total solution preparation time for prep vessel
1608
preparation cycles per batch
2704
determine the cumulative total solution preparation time for each solution by multiplying its total solution preparation time by its respective number of preps per batch or 1
2706
determine the cummulative total solution preparation times for each prep vessel
2708
cumulative total solution preparation time for each solution

FIG. 27

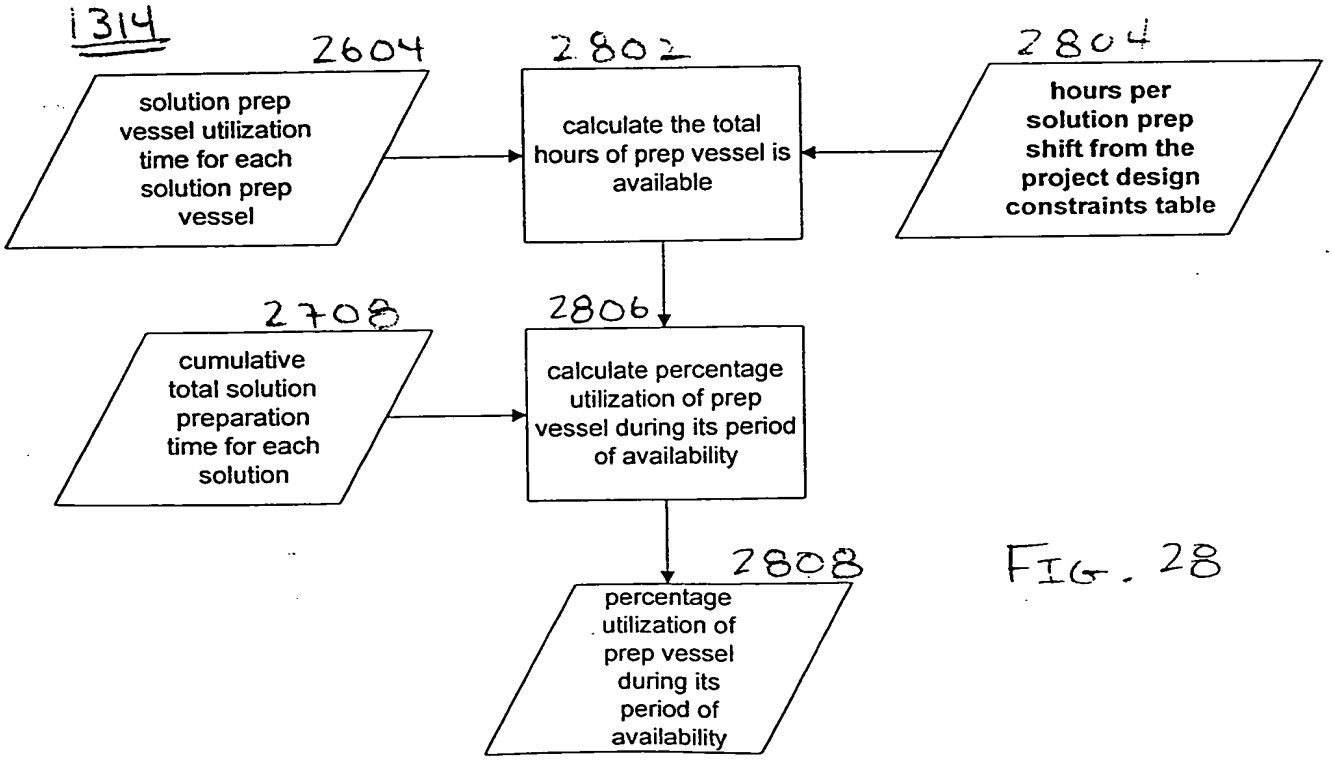
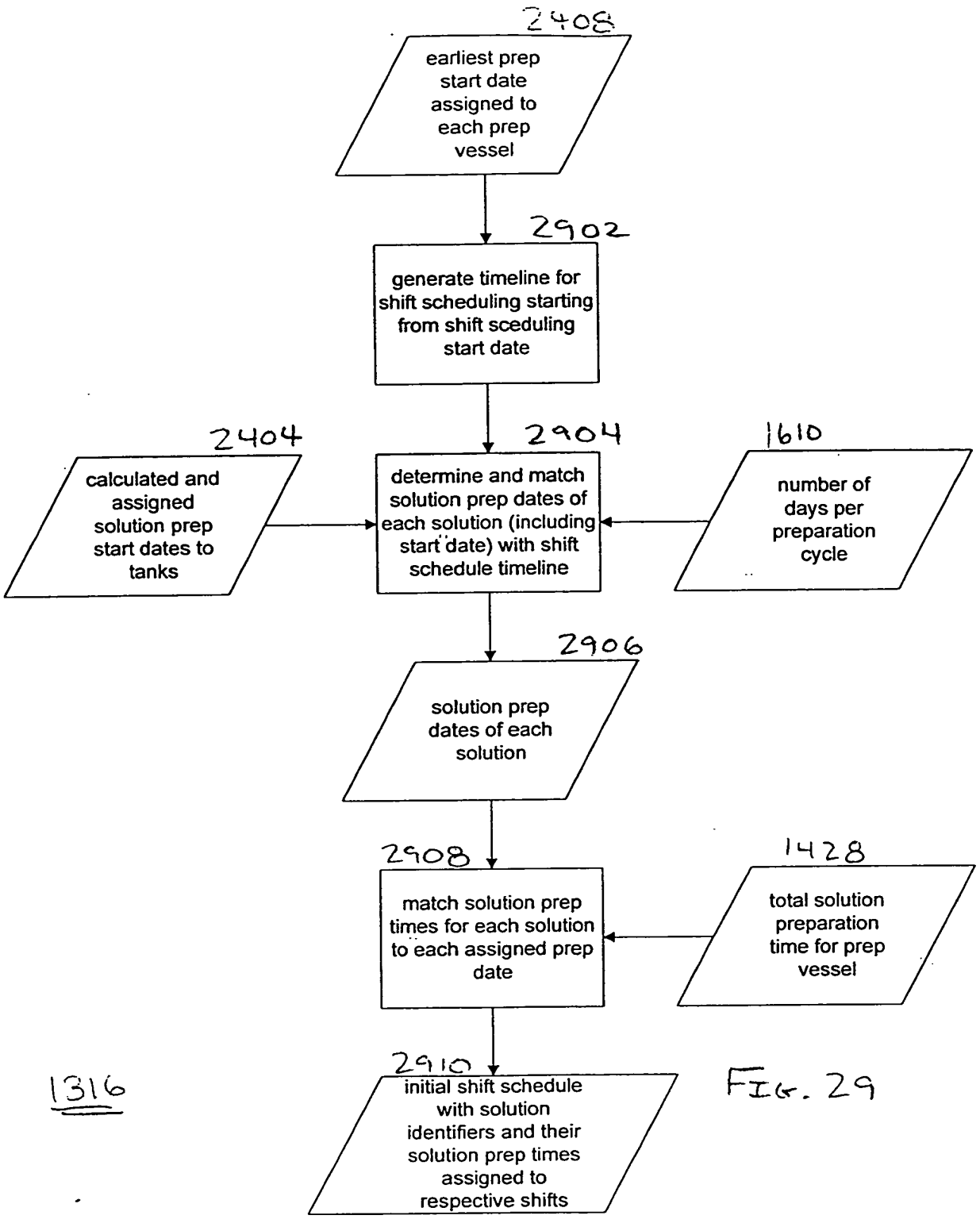

1314
2604
solution prep vessel utilization time for each solution prep vessel
2802
calculate the total hours of prep vessel is available
2804
hours per solution prep shift from the project design constraints table
2708
cumulative total solution preparation time for each solution
2806
calculate percentage utilization of prep vessel during its period of availability
2808
percentage utilization of prep vessel during its period of availability

FIG. 28


2408
earliest prep start date assigned to each prep vessel
2902
generate timeline for shift scheduling starting from shift sceduling start date
2404
calculated and assigned solution prep start dates to tanks
2904
determine and match solution prep dates of each solution (including start date) with shift schedule timeline
1610
number of days per preparation cycle
2906
solution prep dates of each solution
2908
match solution prep times for each solution to each assigned prep date
1428
total solution preparation time for prep vessel
2910
initial shift schedule with solution identifiers and their solution prep times assigned to respective shifts

1316

FIG. 29

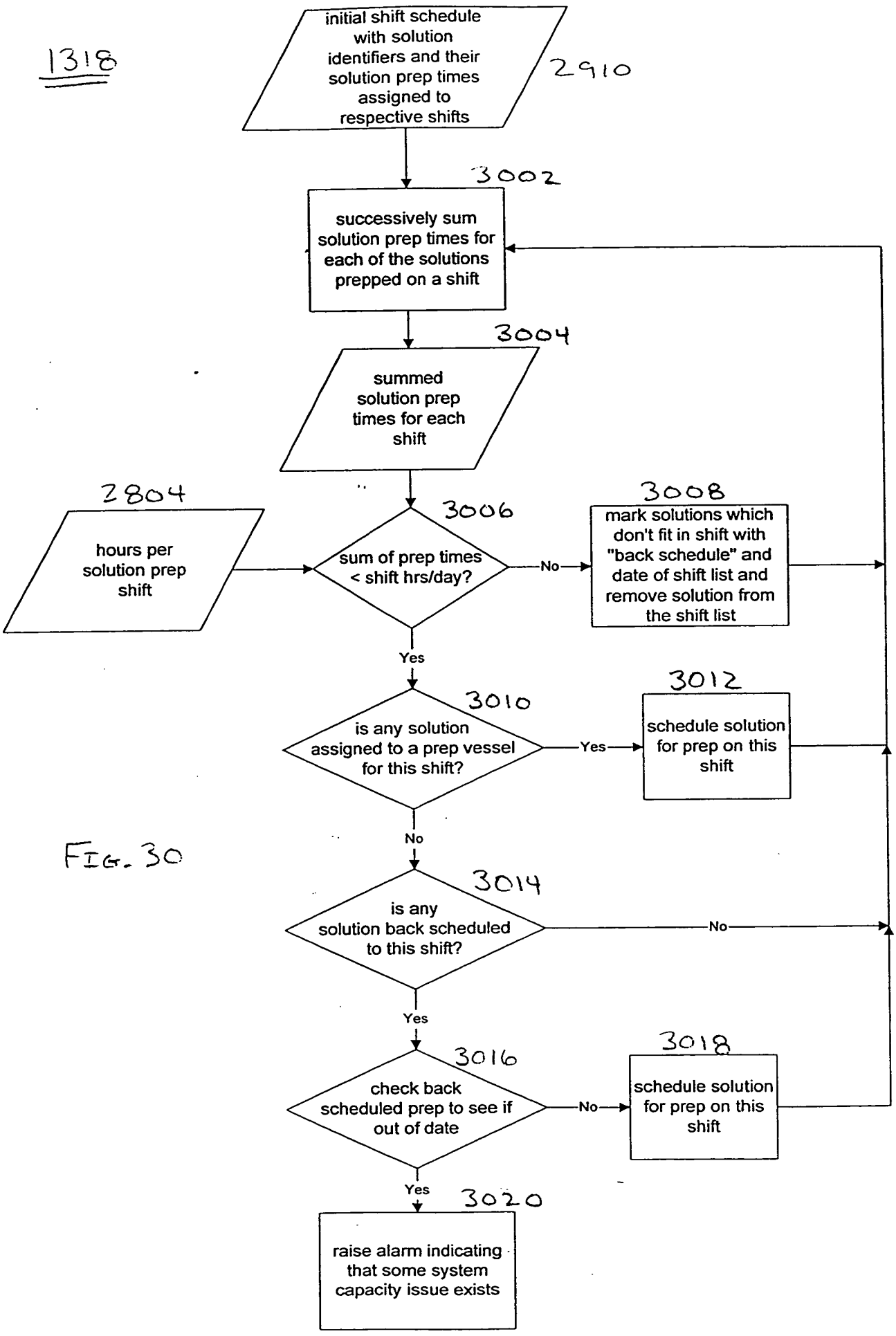

1318
initial shift schedule with solution identifiers and their solution prep times assigned to respective shifts
2910
3002
successively sum solution prep times for each of the solutions prepped on a shift
3004
summed solution prep times for each shift
2804
hours per solution prep shift
3006
sum of prep times < shift hrs/day?
No
3008
mark solutions which don't fit in shift with "back schedule" and date of shift list and remove solution from the shift list
Yes
3010
is any solution assigned to a prep vessel for this shift?
Yes
3012
schedule solution for prep on this shift
No
3014
is any solution back scheduled to this shift?
No
Yes
3016
check back scheduled prep to see if out of date
No
3018
schedule solution for prep on this shift
Yes
3020
raise alarm indicating that some system capacity issue exists

FIG. 30

2804

Solution Prep Shift Schedule - Solution Prep Vessel 101

		8 Hrs/Day		59		60		61		62		63		64		65		66		67		68	
Tank 101 Usage		3.5	06/13/96 04/06/96	06/03/96		06/04/96		06/05/96		06/06/96		06/07/96		06/08/96		06/08/96		06/10/96		06/11/96		06/12/96	
Soln.		Period	Start	Date	Hrs.	Date	Hrs.	Date	Hrs.	Date	Hrs.	Date	Hrs.	Date	Hrs.	Date	Hrs.	Date	Hrs.	Date	Hrs.	Date	Hrs.
S-0101																							
S-0102	13.2	56	02/14/96	04/10/96		04/10/96		06/05/96	3.5	06/05/96		06/05/96		06/05/96		06/05/96		06/05/96		06/05/96		06/05/96	
S-0103	1.7	7	05/22/96	05/29/96		05/29/96		06/05/96	3.5	06/05/96		06/05/96		06/05/96		06/05/96		06/05/96		06/05/96		06/12/96	3.5
S-0104	8.3	7	05/22/96	05/29/96		05/29/96		06/05/96	3.5	06/05/96		06/05/96		06/05/96		06/05/96		06/05/96		06/05/96		06/12/96	3.5
S-0105	8.3	7	05/22/96	05/29/96		05/29/96		06/05/96	3.5	06/05/96		06/05/96		06/05/96		06/05/96		06/05/96		06/05/96		06/12/96	3.5
S-0106																							
S-0107																							
S-0108																							
S-0109	22.2	7	05/29/96	05/29/96		05/29/96		06/05/96	3.5	06/05/96		06/05/96		06/05/96		06/05/96		06/05/96		06/05/96		06/12/96	3.5
S-0111																							
S-0112																							
S-0113																							
S-0114																							
S-0115																							
S-0116																							
S-0117																							
S-0118																							
S-0119																							
S-0120																							
S-0121																							
S-0122	0.0	7	05/29/96	05/29/96		05/29/96		06/05/96	3.5	06/05/96		06/05/96		06/05/96		06/05/96		06/05/96		06/05/96		06/12/96	3.5
					0		0		21		0		0		0		0		0		0		17.5

3102 1610 2906

FIG. 31

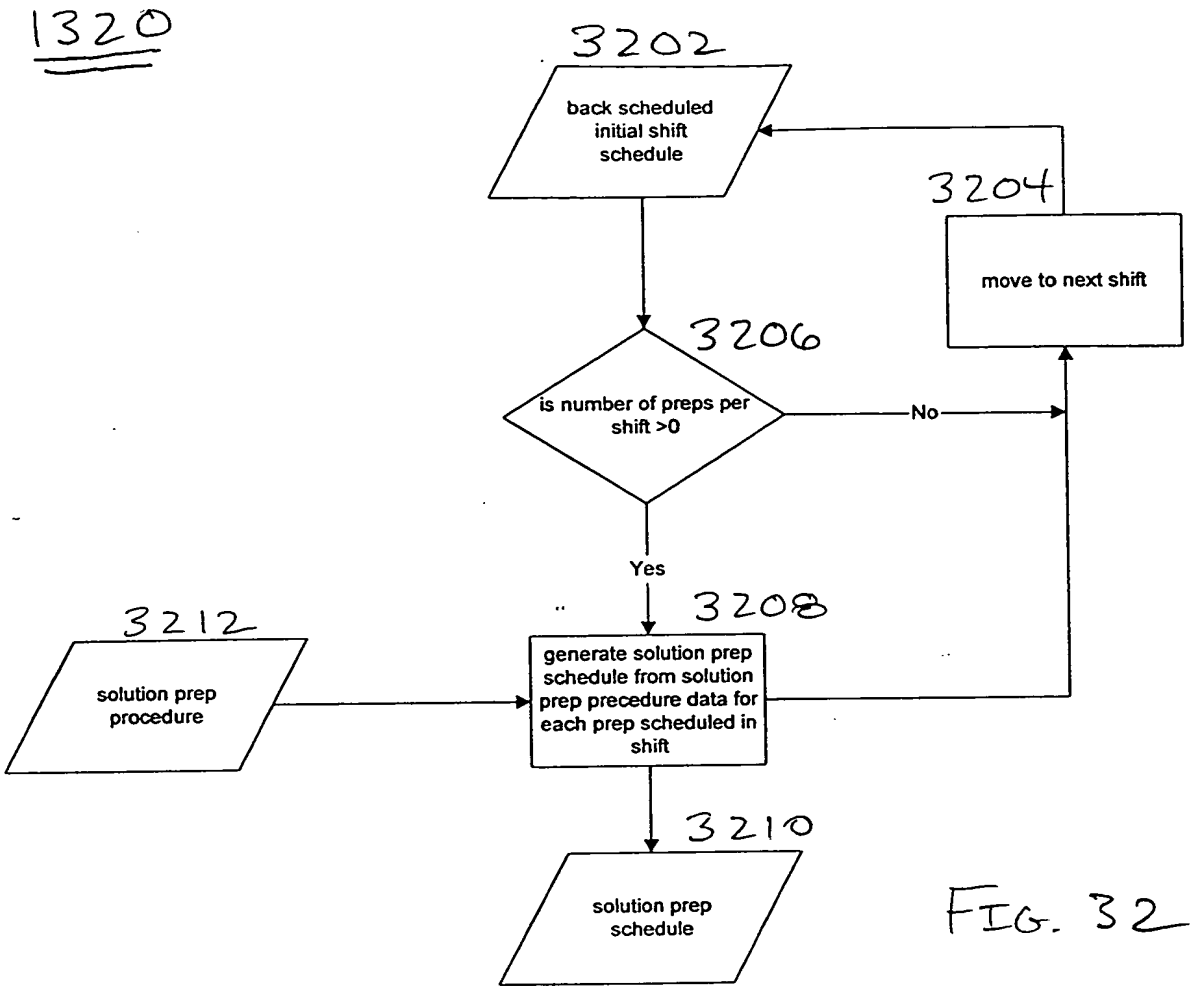
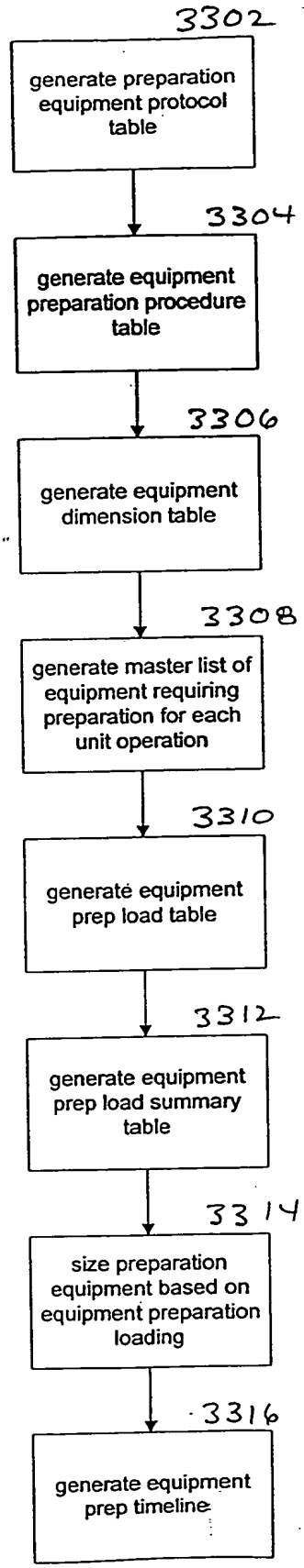

1320
3202
back scheduled initial shift schedule
3204
move to next shift
3206
is number of preps per shift >0
No
Yes
3208
generate solution prep schedule from solution prep precedure data for each prep scheduled in shift
3212
solution prep procedure
3210
solution prep schedule

FIG. 32

FIG. 33


3302
generate preparation equipment protocol table
3304
generate equipment preparation procedure table
3306
generate equipment dimension table
3308
generate master list of equipment requiring preparation for each unit operation
3310
generate equipment prep load table
3312
generate equipment prep load summary table
3314
size preparation equipment based on equipment preparation loading
3316
generate equipment prep timeline

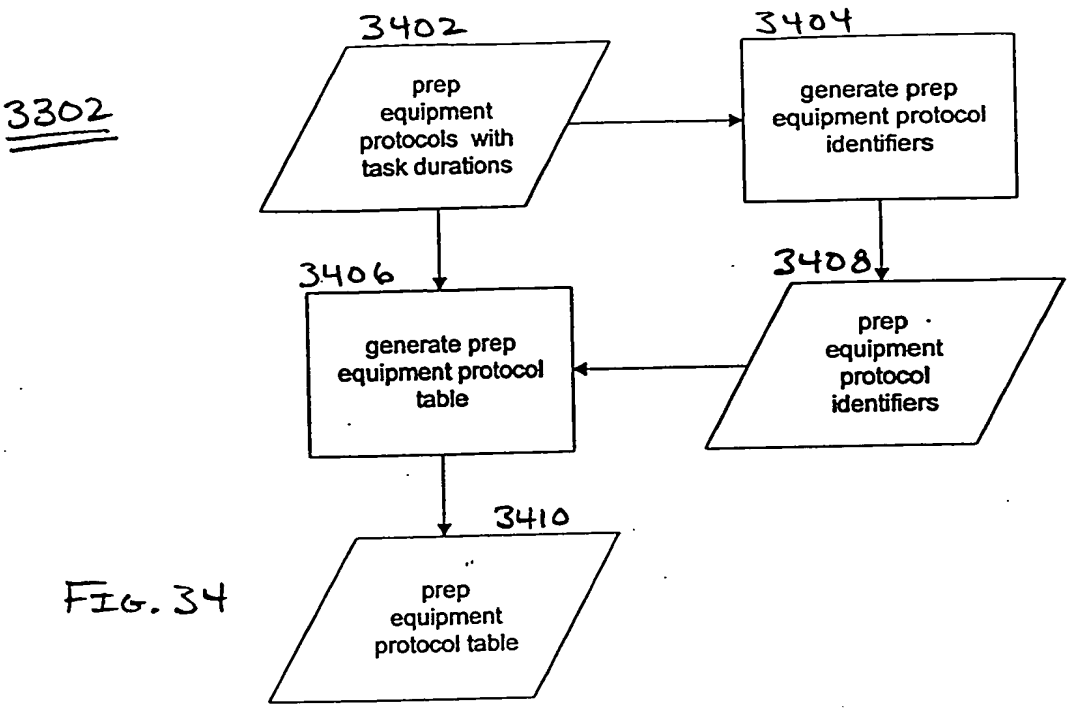

3302
3402
prep equipment protocols with task durations
3404
generate prep equipment protocol identifiers
3406
generate prep equipment protocol table
3408
prep equipment protocol identifiers
3410
prep equipment protocol table

FIG. 34

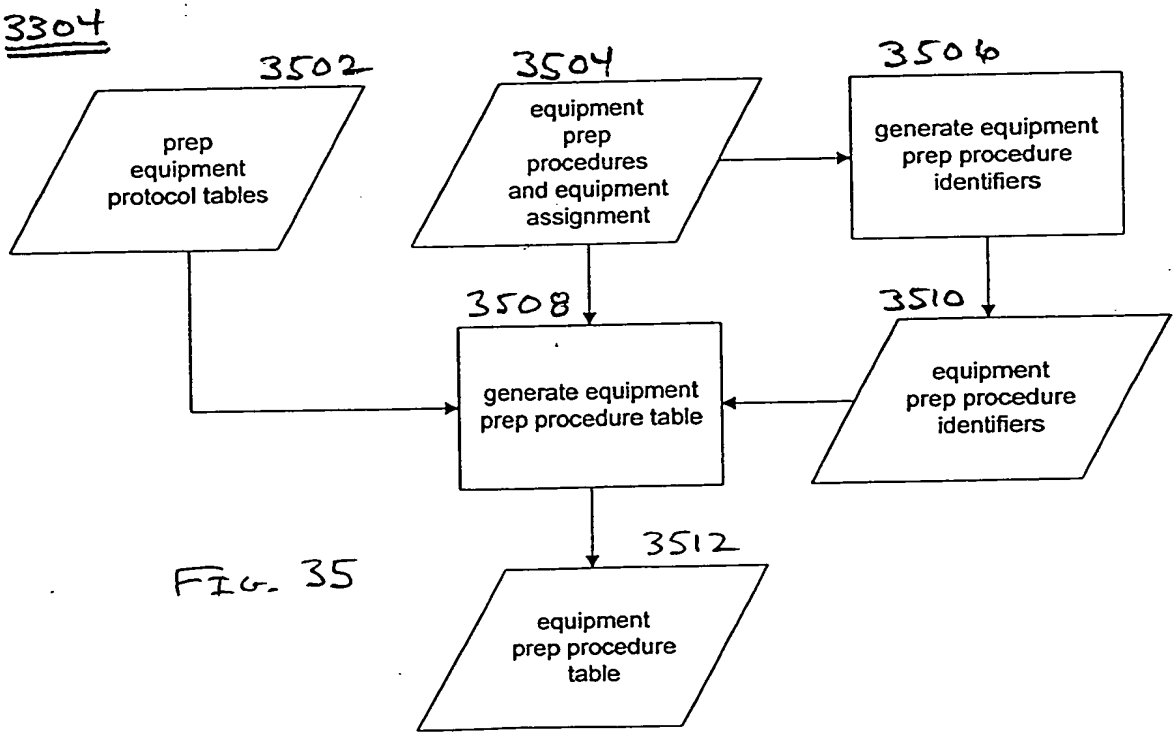

3304
3502
prep equipment protocol tables
3504
equipment prep procedures and equipment assignment
3506
generate equipment prep procedure identifiers
3508
generate equipment prep procedure table
3510
equipment prep procedure identifiers
3512
equipment prep procedure table

FIG. 35

Prep Equipment Protocol - Bench Sink

3408 3602 3604

	Cycle Codes	Minutes/Cycle										Total
		Load	Pre Wash Rinse		Detergent Wash			Post Wash Rinse		Final Rinse	Hold/ Dry	
			NPHW	NPCW	Minutes	Reagent	Gm/CF	NPHW	NPCW			
1	BS-1	5	2	2	5	Alconox	0.5	2	2	2		20
2	BS-2	5	2	2	5	Alconox	0.5	2	2	2		20
3	BS-3	5	2	2	5	Alconox	0.5	2	2	2		20
4	BS-4	5	2	2	5	Alconox	0.5	2	2	2		20
5	BS-5	5	2	2	6	Alconox	0.5	2	2	2		20

FIG. 36A

Prep Equipment Protocol - Wash Station

3408

	Protocol Cycle Code	Minutes/Cycle Load	Pre Wash Rinse NPHW	Pre Wash Rinse NPCW	Detergent Wash Minutes	Detergent Wash Reagent	Detergent Wash Gm/CF	Post Wash Rinse NPHW	Post Wash Rinse NPCW	Final Rinse	Total
1	WS-1	5	2	2	5	Alconox	0.5	2	2	2	15
2	WS-2	5	2	2	6	Alconox	0.5	2	2	2	15
3	WS-3	5	2	2	5	Alconox	0.5	2	2	2	15
4	WS-4	5	2	2	5	Alconox	0.5	2	2	2	15
5	WS-5	5	2	2	5	Alconox	0.5	2	2	2	15

FIG. 36B

Prep Equipment Protocol - Glassware Washer

3408

	Cycle Code	Minutes/Cycle										
		Load	Pre Wash Rinse		Detergent Wash			Post Wash Rinse		Final Rinse	Unload	Total
			NPHW	NPCW	Minutes	Reagent	Gm/CF	NPHW	NPCW			
1	GW-1	15	2	2	5	Alconox	0.5	2	2	2	10	40
2	GW-2	15	2	2	5	Alconox	0.5	2	2	2	10	40
3	GW-3	15	2	2	5	Alconox	0.5	2	2	2	10	40
4	GW-4	15	2	2	5	Alconox	0.5	2	2	2	10	40
5	GW-5	15	2	2	5	Alconox	0.5	2	2	2	10	40

FIG. 36C

Prep Equipment Protocol - Glassware Dryer

3408

	Cycle Code	Load	Heat Up Minutes	Dry		Cool Minutes	Unload	Total
				Temp (C)	Minutes			
1	DO-1	10	30	250	40	30	10	120
2	DO-2	10	30	250	25	30	10	105
3	DO-3	10	30	250	25	30	10	105
4	DO-4	10	30	250	25	30	10	105
5	DO-5	10	30	250	25	30	10	105

3618 3620 3622 3624 3626 3628

FIG. 36D

Prep Equipment Protocol - Carboy Washer

3408

1.55'x

Minutes/Cycle

Load	Pre Wash Rinse		Detergent			Post Wash Rinse		Final Rinse	Unload	Total
	NPHW	NPCW	Minutes	Reagent	Gm/CF	NPHW	NPCW			
15	2	2	5	Alconox	0.5	2	2	2	15	15
15	2	2	5	Alconox	0.5	2	2	2	15	15
15	2	2	5	Alconox	0.5	2	2	2	15	15
15	2	2	5	Alconox	0.5	2	2	2	15	15
15	2	2	5	Alconox	0.5	2	2	2	15	15
15	2	2	5	Alconox	0.5	2	2	2	15	15

FIG. 36E

Prep Equipment Protocol - Carboy Dryer

3408

	Cycle Code	Load	Heat Up Minutes	Dry		Cool Minutes	Unload	Total
				Temp (C)	Minutes			
1	CD-1	10	30	250	40	30	10	100
2	CD-2	10	30	250	25	30	10	85
3	CD-3	10	30	250	25	30	10	85
4	CD-4	10	30	250	25	30	10	85
5	CD-5	10	30	250	25	30	10	85

FIG. 36F

Prep Equipment Protocol - Steam Sterilizer

		Cycles														
		SS-1					SS-2					SS-3				
		Press. (Bar)	Minutes To Ach.	Minutes To Hold	No. of Cycles	Subt.	Press. (Bar)	Minutes To Ach.	Minutes To Hold	No. of Cycles	Subt.	Press. (Bar)	Minutes To Ach.	Minutes To Hold	No. of Cycles	Subt.
1	Load					20					20					20
2																
3	Pre Sterilization															
4	Deep Vacuum		15	1	1	16										
5	Vacuum/Steam Pulse							3	0	9	27		3	0	9	27
6	Vacuum						1	2	0	9	18	1	2	0	9	18
7	Steam										45					45
8	Subtotal					16										
9																
10	Sterilization															
11	Steam	1	20	40	1	60	1	20	40	1	60	1	20	40	1	60
12	Steam/Air															
13	Subtotal					60					60					60
14																
15	Cooling															
16	Direct Air Cooling											0	40	0	1	40
17	Indirect Jacket Cooling	0	40	0	1	40	0	40	0	1	40	1	40	0	1	40
18	Overpressure															80
19	Subtotal					40					40					
20																
21	Drying															
22	Fast Exhaust	0	20	5	1	25						0	20	5	1	25
23	Slow Exhaust															
24	Deep Vacuum							3	0	10	30					
25	Vacuum Pulse															
26	Heat															
27	Healed Pressure															25
28	Subtotal					25					30					
29																20
30	Unload					20					20					
31											195					230
32	Total Minutes					161					3.3					3.8
33	Total Hours					2.7										

FIG. 36G

Prep Equipment Protocol - Dry Heat Sterilizer

340°

	Cycle Code	Load	Heat Up Minutes	Sterilization		Cool Minutes	Unload	Total
				Temp (C)	Minutes			
1	SO-1	15	30	250	40	30	15	130
2	SO-2	15	30	260	25	30	15	115
3	SO-3	15	30	250	25	30	15	115
4	SO-4	15	30	250	25	30	15	115
5	SO-5	15	30	250	25	30	15	115

FIG. 36H

3706

3702

3704

~~Prep Equipment Protocol~~ - Equipment Prep Procedures

			EPC1	EPC2	EPC3	EPC4	EPC5	EPC6	EPC7
1	Initial Rinse								
2									
3	Bench Sink - 1								
4	Procedure		BS-1	BS-1	BS-2	BS-1			
5	Duration	PHrs.	0.33	0.33	0.33	0.33			
6	Hold/Dry	PHrs.	0	0	0				
7	Subtotal	PHrs.	0.33	0.33	0.33	0.33	0.00	0.00	0.00
8	Cummulative	PHrs.	0.33	0.33	0.33	0.33	0.00	0.00	0.00
9									
10	Wash Station - 1								
11	Procedure						WS-1	WS-1	
12	Duration	PHrs.					0.25	0.25	
13	Hold/Dry	PHrs.							
14	Subtotal	PHrs.	0.00	0.00	0.00	0.00	0.25	0.25	0.00
15	Cummulative	PHrs.	0.33333	0.33333	0.33333	0.33333	0	0	0
16									
17	Cleaning								
18									
19	Bench Sink - 1								
20	Procedure		BS-3	BS-3	BS-4				
21	Duration	PHrs.	0.33	0.33	0.33				
22	Hold/Dry	PHrs.							
23	Subtotal	PHrs.	0.33	0.33	0.33	0.00	0.00	0.00	0.00
24	Cummulative	PHrs.	0.66667	0.66667	0.66667	0.33333	0	0	0
25									
26	Glassware Washer - 1								
27	Procedure					GW-1			
28	Duration	PHrs.				0.67			
29	Hold/Dry	PHrs.							
30	Subtotal	PHrs.	0.00	0.00	0.00	0.67	0.00	0.00	0.00
31	Cummulative	PHrs.	0.66667	0.66667	0.66667	1	0	0	0
32									
33	Glassware Dryer - 1								
34	Procedure		GD-1	GD-1	GD-2	GD-3			
35	Duration	PHrs.	2.00	2.00	1.75	1.75			
36	Hold/Dry	PHrs.							
37	Subtotal	PHrs.	2.00	2.00	1.75	1.75	0.00	0.00	0.00
38	Cummulative	PHrs.	2.66667	2.66667	2.41667	2.75	0	0	0
39									
40	Carboy Washer - 1								
41	Procedure						CW-1	CW-1	
42	Duration	PHrs.					0.25	0.25	
43	Hold/Dry	PHrs.							
44	Subtotal	PHrs.	0.00	0.00	0.00	0.00	0.25	0.25	0.00
45	Cummulative	PHrs.	2.66667	2.66667	2.41667	2.75	0.25	0.25	0
46									
47	Carboy Dryer - 1								
48	Procedure						CD-1	CD-1	
49	Duration	PHrs.					1.67	1.67	
50	Hold/Dry	PHrs.							
51	Subtotal	PHrs.	0.00	0.00	0.00	0.00	1.67	1.67	0.00
52	Cummulative	PHrs.	2.66667	2.66667	2.41667	2.75	1.91667	1.91667	0
53									
54	Prep								
55									
56	Staffing		2	2	2	2	2	2	2
57									
58	Preassembly								
59	Man Hours	MHrs.		1					
60	Procudure Hours			0.5					

FIG. 37A

Prep Equipment Protocol - Equipment Prep Procedures

			EPC1	EPC2	EPC3	EPC4	EPC5	EPC6	EPC7
61	Cummulative	PHrs.	2.66667	3.16667	2.41667	2.75	1.91667	1.91667	0
62									
63	Wrap								
64	Man Hours	MHrs.	1.5	1.5	1.5	1.5	1.5	1.5	1.5
65	Procedure Hours		0.75	0.75	0.75	0.75	0.75	0.75	0.75
66	Cummulative	PHrs.	3.41667	3.91667	3.16667	3.5	2.66667	2.66667	0.75
67									
68	Sterilization								
69									
70	Autoclave - 1								
71	Procedure		SS-1	SS-1	SS-1	SS-1	SS-2		SS-3
72	Duration	PHrs.	2.68	2.68	2.68	2.68	3.25		3.83
73	Hold/Dry	PHrs.							
74	Subtotal	PHrs.	2.68	2.68	2.68	2.68	3.25	0.00	3.83
75	Cummulative	PHrs.	6.10	6.60	5.85	6.18	5.92	2.67	4.58
76									
77	Dry Heat - 1							SO-1	
78	Procedure							2.17	
79	Hours/Load	PHrs.							
80	Hold/Dry	PHrs.							
81	Subtotal	PHrs.	0.00	0.00	0.00	0.00	0.00	2.17	0.00
82	Cummulative	PHrs.	6.10	6.60	5.85	6.18	5.92	4.83	4.58
83									
84	Total		6.10	6.60	5.85	6.18	6.17	5.08	4.58
85									
86	Max		2.68	2.68	2.68	2.68	3.25	2.17	3.83

FIG. 37B

3306

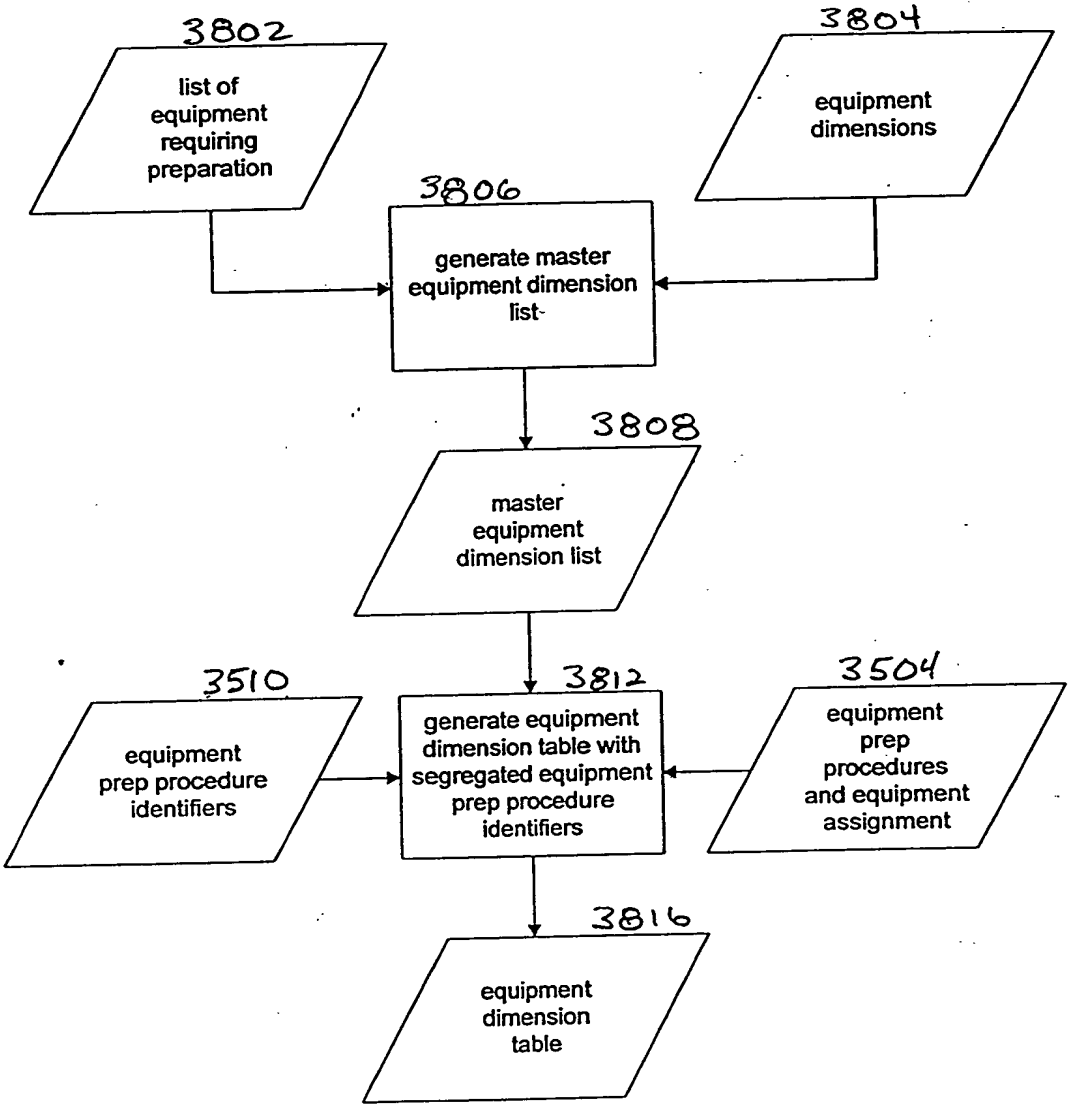
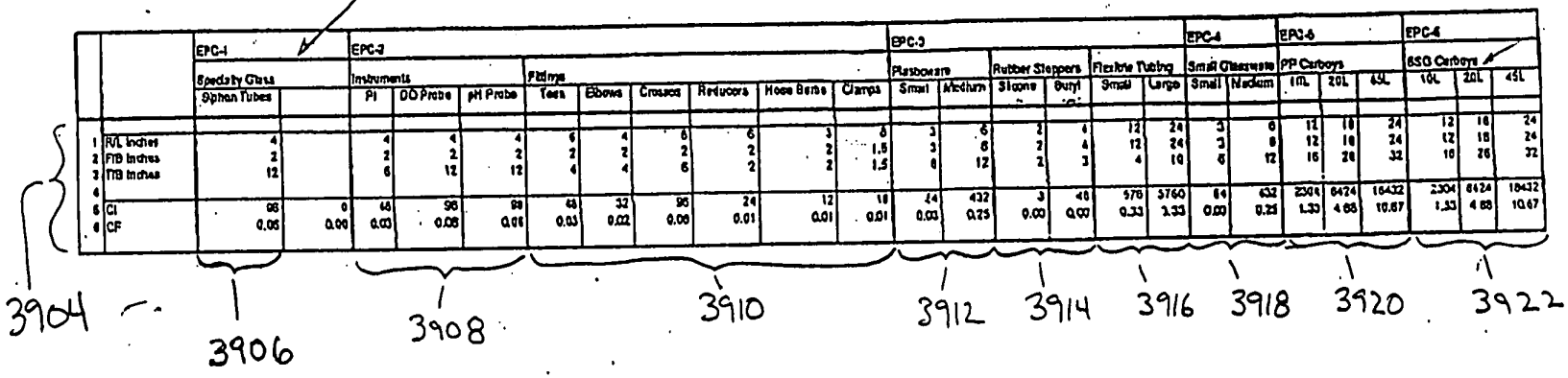

3802
list of equipment requiring preparation
3804
equipment dimensions
3806
generate master equipment dimension list
3808
master equipment dimension list
3510
equipment prep procedure identifiers
3812
generate equipment dimension table with segregated equipment prep procedure identifiers
3504
equipment prep procedures and equipment assignment
3816
equipment dimension table

FIG. 38

Load Configuration Table - General



		EPC-1		EPC-2			EPC-3												EPC-4		EPC-5			EPC-6		
		Specialty Glass		Instruments			Fittings						Plasticware		Rubber Stoppers		Flexible Tubing		Small Glassware		PP Carboys			6SG Carboys		
		Siphon Tubes		PI	DO Probe	pH Probe	Tees	Elbows	Crosses	Reducers	Hose Barbs	Clamps	Small	Medium	Stopper	Bung	Small	Large	Small	Medium	10L	20L	45L	10L	20L	45L
1	R/L Inches	4		4	4	4	6	4	6	6	3	6	3	6	2	4	12	24	3	6	12	18	24	12	18	24
2	FTB Inches	2		2	2	2	2	2	2	2	2	1.5	3	6	2	4	12	24	3	6	12	18	24	12	18	24
3	TTB Inches	12		6	12	12	4	4	6	2	2	1.5	6	12	2	3	4	10	6	12	16	26	32	16	26	32
4																										
5	CI	96	0	48	96	96	48	32	96	24	12	18	24	432	3	48	576	3760	64	632	2304	6424	18432	2304	6424	18432
6	CF	0.06	0.00	0.03	0.06	0.06	0.03	0.02	0.06	0.01	0.01	0.01	0.03	0.25	0.00	0.00	0.33	2.33	0.00	0.35	1.33	4.68	10.67	1.33	4.68	10.67

3902

3904

3906

3908

3910

3912

3914

3916

3918

3920

3922

FIG. 39

3308

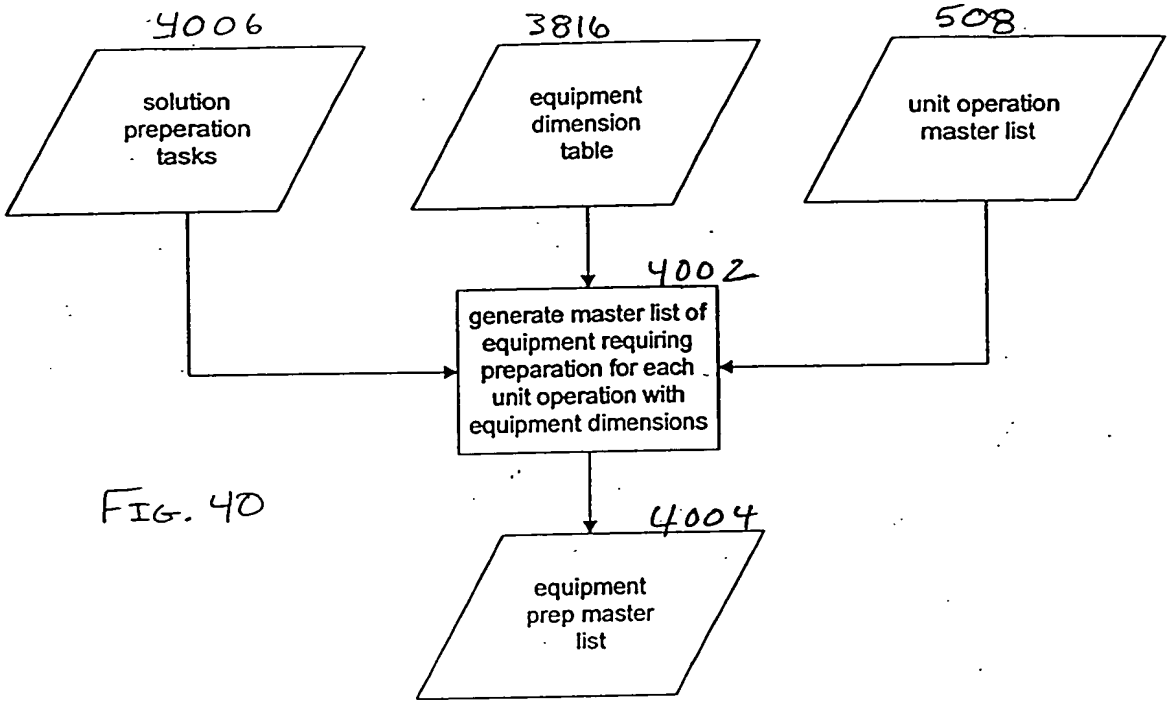


FIG. 40

3310

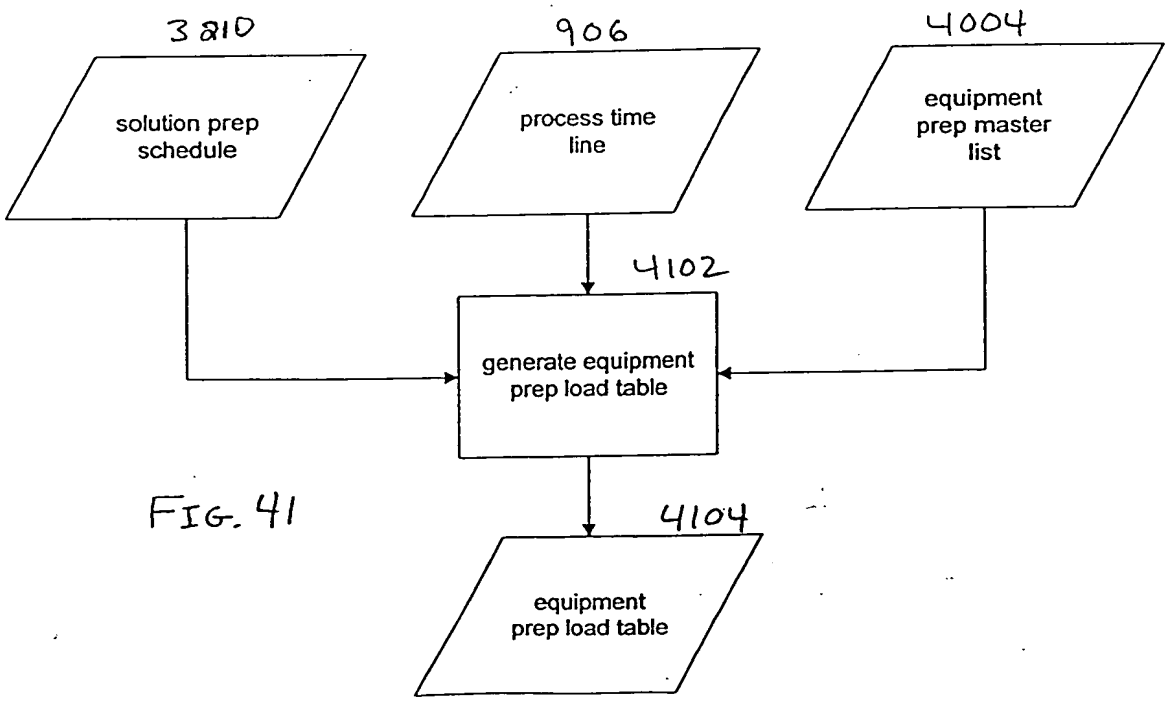


FIG. 41

4202 4204 4206 Equipment Prep Load Table 4208

TASK ~~Equipment Items~~	Unit Oper End Time		EPC-1			EPC-2									Total CF	EPC-3
			Specialty Glass			Instruments			Fittings							Plasticware
	Date	Time	Siphon Tubes		Total	PI 0.03	DO Probe 0.06	pH Probe 0.06	Tees 0.03	Elbows 0.02	Crosses 0.06	Reducers 0.01	Hose Barbs 0.01	Clamps 0.01		Beakers 0.03
1 Inoculum Prep	06/04/96	02:30 PM			0										0.00	
2 Flask Growth	06/05/96	01:30 PM			0										0.00	
3 Seed Fermentation	06/06/96	03:30 PM			0										0.00	
4 Fermentation	06/07/96	12:00 PM			0	4 0.111			6 0.17			2 0.03	4 0.03	16 0.17	0.50	
5 Heat Exchange	06/07/96	01:00 PM			0	3			4 0.11				4 0.03	8 0.08	0.22	
6 Cont. Cent/Solids	06/07/96	11:51 AM			0	3 0.083			4 0.11				4 0.03	8 0.08	0.31	
1 Inoculum Prep	06/06/96	02:30 PM			0										0.00	
2 Flask Growth	06/07/96	01:30 PM			0										0.00	
3 Seed Fermentation	06/08/96	03:30 PM			0										0.00	
4 Fermentation	06/09/96	09:00 AM			0	4 0.111			6 0.17			2 0.03	4 0.03	16 0.17	0.50	
5 Heat Exchange	06/09/96	10:00 AM			0	3 0.083			4 0.11				4 0.03	8 0.08	0.31	
6 Cont. Cent/Solids	06/09/96	08:51 AM			0	3 0.083			4 0.11				4 0.03	8 0.08	0.31	
1 Inoculum Prep	06/08/96	02:30 PM			0										0.00	
2 Flask Growth	06/09/96	01:30 PM			0										0.00	
3 Seed Fermentation	06/10/96	03:30 PM			0										0.00	
4 Fermentation	06/03/96	10:00 AM			0	4 0.111			6 0.17			2 0.03	4 0.03	16 0.17	0.50	
5 Heat Exchange	06/11/96	09:00 AM			0	3 0.083			4 0.11				4 0.03	8 0.08	0.31	
6 Cont. Cent/Solids	06/11/96	08:51 AM			0	3 0.083			4 0.11				4 0.03	8 0.08	0.31	
7 Cell Resuspension	06/11/96	12:15 PM			0										0.00	
8 Heat Exchange	06/11/96	09:33 AM			0										0.00	
9 Cell Disruption	06/11/96	09:51 AM			0										0.00	
10 Heat Exchange	06/11/96	10:09 AM			0										0.00	

Fig. 4A

4210 4212 4214 4216

Equipment Items	Unit Oper End Time								EPC-4			EPC-5				EPC-6			
	Date	Time	Flasks 0.25	Rubber Stoppers Silicone 0.00	Rubber Stoppers Butyl 0.03	Flexible Tubing Silicone 0.33	Flexible Tubing Neoprene 3.33	Total CF	Small Glassware Beakers 0.03125	Small Glassware Flasks 0.25	Total CF	PP Carboys 10L 1.3333	PP Carboys 20L 4.88	PP Carboys 45L 10.7	Total CF	BSG Carboys 10L 1.3333	BSG Carboys 20L 4.88	BSG Carboys 45L 10.7	Total CF
1 Inoculum Prep	06/04/96	02:30 PM						0.00		5 1.25	1.25				0.00				0.00
2 Flask Growth	06/05/96	01:30 PM						0.00		5 1.25	1.25				0.00				0.00
3 Seed Fermentation	06/06/96	03:30 PM		4 0.02		4 1.33		1.35		4 1.00	1				0.00				0.00
4 Fermentation	06/07/96	12:00 PM		4 0.02		4 1.33		1.35			0	4 5.33			5.33				0.00
5 Heat Exchange	06/07/96	01:00 PM						0.00			0				0.00				0.00
6 Cont. Cent/Solids	06/07/96	11:51 AM						0.00			0				0.00				0.00
1 Inoculum Prep	06/06/96	02:30 PM						0.00		5 1.25	1.25				0.00				0.00
2 Flask Growth	06/07/96	01:30 PM						0.00		5 1.25	1.25				0.00				0.00
3 Seed Fermentation	06/08/96	03:30 PM						0.00			0				0.00				0.00
4 Fermentation	06/09/96	09:00 AM						0.00			0				0.00				0.00
5 Heat Exchange	06/09/96	10:00 AM						0.00			0				0.00				0.00
6 Cont. Cent/Solids	06/09/96	08:51 AM						0.00			0				0.00				0.00
1 Inoculum Prep	06/08/96	02:30 PM						0.00		5 1.25	1.25				0.00				0.00
2 Flask Growth	06/09/96	01:30 PM						0.00		5 1.25	1.25				0.00				0.00
3 Seed Fermentation	06/10/96	03:30 PM						0.00			0				0.00				0.00
4 Fermentation	06/03/96	10:00 AM						0.00			0				0.00				0.00
5 Heat Exchange	06/11/96	09:00 AM						0.00			0				0.00				0.00
6 Cont. Cent/Solids	06/11/96	08:51 AM						0.00			0				0.00				0.00
7 Cell Resuspension	06/11/96	12:15 PM						0.00			0				0.00				0.00
8 Heat Exchange	06/11/96	09:33 AM						0.00			0				0.00				0.00
9 Cell Disruption	06/11/96	09:51 AM						0.00			0				0.00				0.00
10 Heat Exchange	06/11/96	10:09 AM						0.00		5 1.25	1.25				0.00				0.00

FIG. 42B

Equipment Prep Load Table

4218 4220

Equipment Items	Unit Oper End Time		EPC-1			EPC-2										EPC-3
			Specialty Glass			Instruments			Fittings							Plasticware
	Date	Time	Siphon Tubes		Total	PI 0.03	DO Probe 0.06	pH Probe 0.06	Tees 0.03	Elbows 0.02	Crosses 0.06	Reducers 0.01	Hose Barbs 0.01	Clamps 0.01	Total CF	Beakers 0.03
8 Heat Exchange	06/11/96	10:27 AM			0										0.00	
9 Cell Disruption	06/11/96	10:45 AM			0										0.00	
10 Heat Exchange	06/11/96	12:00 AM			0										0.00	
8 Heat Exchange	06/11/96	02:21 PM			0										0.00	
9 Cell Disruption	06/11/96	02:39 PM			0										0.00	
10 Heat Exchange	06/11/96	02:57 PM			0										0.00	
11 IB Resuspension	06/11/96	10:57 AM			0										0.00	
12 Centrifugation	06/11/96	11:33 AM			0										0.00	
11 IB Resuspension	06/11/96	03:06 PM			0										0.00	
12 Centrifugation	06/11/96	03:12 PM			0										0.00	
13 Renaturation	06/12/96	08:43 AM			0										0.00	
14 Buffer Exchange	06/12/96	11:47 AM			0										0.00	
15 Clarification	06/12/96	11:03 AM			0										0.00	
16 Chromatography 1	06/12/96	03:59 PM			0										0.00	
17 Chromatography 2	06/12/96	06:59 PM			0										0.00	
18 Buffer Exchange	06/12/96	08:27 PM			0										0.00	
19 Chromatography 3	06/12/96	10:07 PM			0										0.00	
20 Buffer Exchange	06/12/96	10:38 PM			0										0.00	
21 Chromatography 4	06/13/96	12:14 AM			0										0.00	
22 Sterile Filtration	06/13/96	12:48 AM			0										0.00	
Totals															3.25	

FIG. 42C

Equipment Top Load Table

Equipment Items	Unit Oper End Time		4222						EPC-4			EPC-5				EPC-6			
	Date	Time		Rubber Stoppers		Flexible Tubing		Total CF	Small Glassware		Total CF	PP Carboys			Total CF	BSG Carboys			Total CF
			Flasks 0.25	Silicone 0.00	Butyl 0.03	Silicone 0.33	Neoprene 3.33		Beakers 0.03125	Flasks 0.25		10L 1.3333	20L 4.88	45L 10.7		10L 1.3333	20L 4.88	45L 10.7	
8 Heat Exchange	06/11/96	10:27 AM						0.00			0				0.00				0.00
9 Cell Disruption	06/11/96	10:45 AM						0.00			0				0.00				0.00
10 Heat Exchange	06/11/96	12:00 AM						0.00		5 1.25	1.25				0.00				0.00
8 Heat Exchange	06/11/96	02:21 PM						0.00			0				0.00				0.00
9 Cell Disruption	06/11/96	02:39 PM						0.00			0				0.00				0.00
10 Heat Exchange	06/11/96	02:57 PM						0.00		5 1.25	1.25				0.00				0.00
11 IB Resuspension	06/11/96	10:57 AM						0.00			0				0.00				0.00
12 Centrifugation	06/11/96	11:33 AM						0.00			0				0.00				0.00
11 IB Resuspension	06/11/96	03:06 PM						0.00			0				0.00				0.00
12 Centrifugation	06/11/96	03:12 PM						0.00			0				0.00				0.00
13 Renaturation	06/12/96	08:43 AM						0.00			0				0.00				0.00
14 Buffer Exchange	06/12/96	11:47 AM						0.00			0				0.00				0.00
15 Clarification	06/12/96	11:03 AM						0.00			0				0.00				0.00
16 Chromatography 1	06/12/96	03:59 PM						0.00			0				0.00				0.00
17 Chromatography 2	06/12/96	06:59 PM						0.00			0				0.00				0.00
18 Buffer Exchange	06/12/96	08:27 PM						0.00			0				0.00				0.00
19 Chromatography 3	06/12/96	10:07 PM						0.00			0				0.00				0.00
20 Buffer Exchange	06/12/96	10:38 PM						0.00			0				0.00				0.00
21 Chromatography 4	06/13/96	12:14 AM						0.00			0				0.00				0.00
22 Sterile Filtration	06/13/96	12:48 AM						0.00			0				0.00				0.00
Totals																			

FIG. 42D

3312

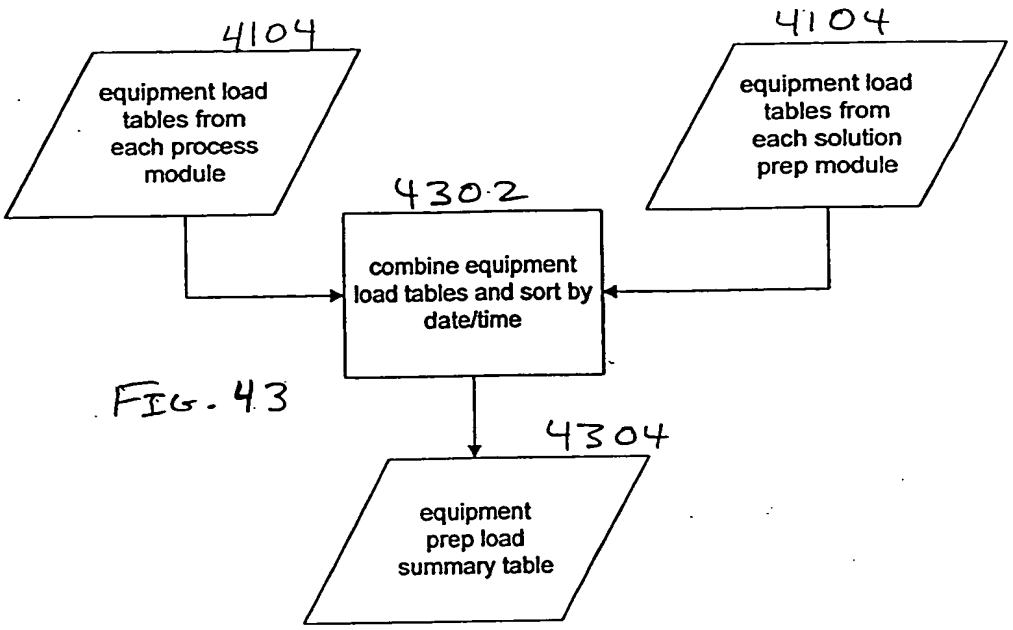

4104
equipment load tables from each process module
4104
equipment load tables from each solution prep module
4302
combine equipment load tables and sort by date/time
4304
equipment prep load summary table

FIG. 43

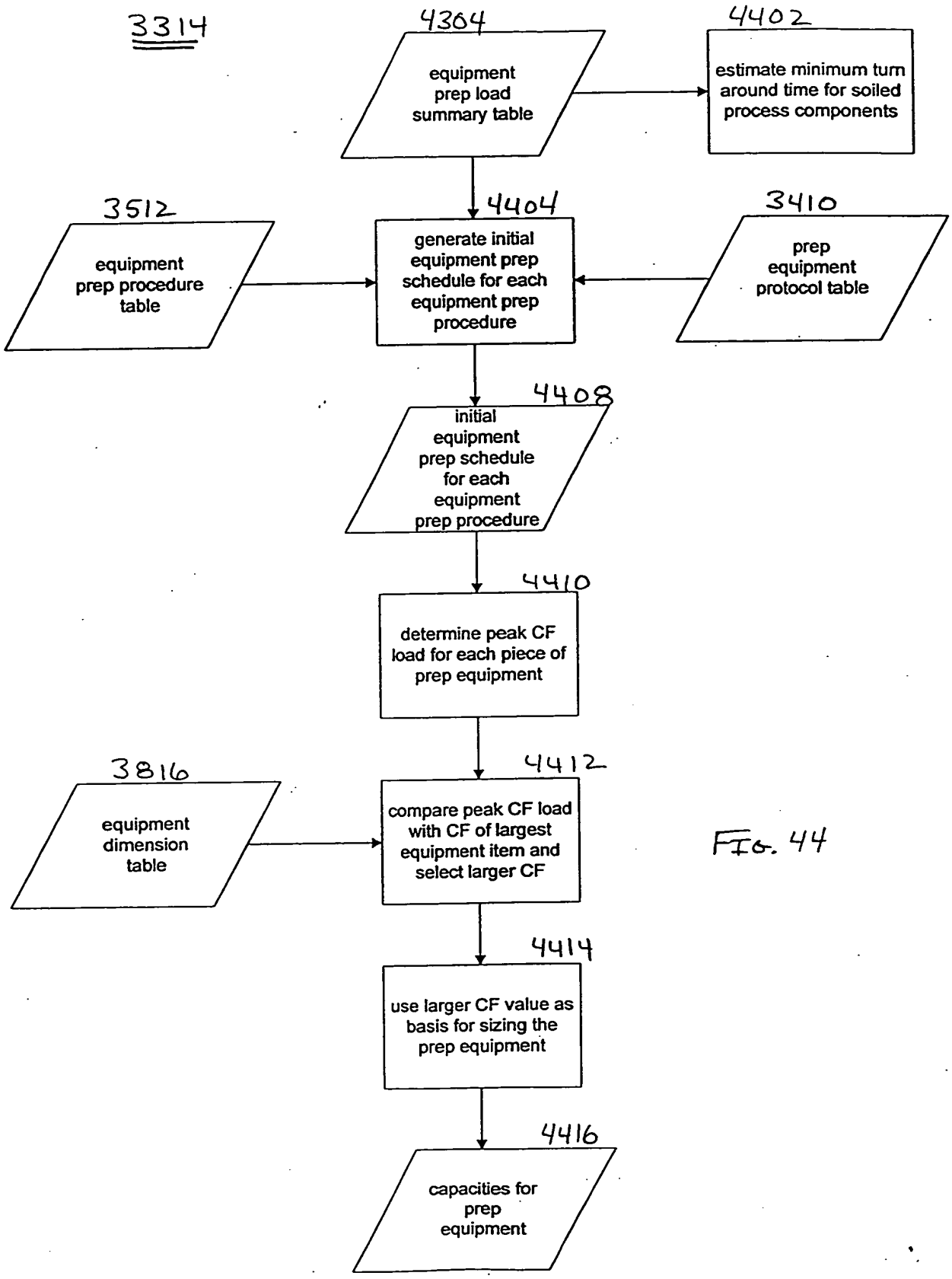

3314
4304
equipment prep load summary table
4402
estimate minimum turn around time for soiled process components
3512
equipment prep procedure table
4404
generate initial equipment prep schedule for each equipment prep procedure
3410
prep equipment protocol table
4408
initial equipment prep schedule for each equipment prep procedure
4410
determine peak CF load for each piece of prep equipment
3816
equipment dimension table
4412
compare peak CF load with CF of largest equipment item and select larger CF
4414
use larger CF value as basis for sizing the prep equipment
4416
capacities for prep equipment

FIG. 44

4.502 4.504 QC Load Table - PE Module 4506

	Operation	Start		Finish		QA/QC Samples																	
						Visual		Chemical						Biochemical							Immulogical		Act.
		Date	Time	Date	Time	AV-1	AV-2	AC-1	AC-2	AC-3	AC-4	AC-5	AC-6	AB-1	AB-2	AB-3	AB-4	AB-5	AB-6	AB-7	AI-1	AI-2	AA-1
		06/03/96	08:00 AM																				
1	1 A Inoculum Prep																						
2																							
3	Set Up	06/03/96	09:30 AM	06/03/96	12:30 PM																		
4	Preincubation	06/03/96	12:30 PM	06/03/96	03:30 PM																		
5	Incubation	06/03/96	03:30 PM	06/04/96	02:30 PM																		
6	Clean Up	06/04/96	02:30 PM	06/04/96	02:45 PM																		
6	Subtotal																						
7																							
8	2 A Flask Growth																						
9																							
10	Set Up	06/04/96	12:30 PM	06/04/96	01:30 PM																		
11	Preincubation	06/04/96	01:30 PM	06/04/96	02:30 PM																		
12	Incubation	06/04/96	02:30 PM	06/05/96	01:30 PM																		
13	Clean Up	06/05/96	01:30 PM	06/05/96	01:45 PM																		
13	Subtotal																						
14																							
15	3 A Seed Fermentation																						
16																							
17	Set Up	06/05/96	11:30 AM	06/05/96	12:30 PM																		
18	Preincubation	06/05/96	12:30 PM	06/05/96	01:30 PM																		
19	Fermentation	06/05/96	01:30 PM	06/06/96	10:30 AM		2																
20	Harvest	06/06/96	10:30 AM	06/06/96	11:00 AM																		
21	CIP	06/06/96	10:30 AM	06/06/96	11:30 AM																		
22	SIP	06/06/96	11:30 AM	06/06/96	12:30 PM																		
23	Clean Up	06/06/96	12:30 PM	06/06/96	03:30 PM																		
24	Subtotal																						
25																							
26	4 A Production Fermentation																						
27																							
28	Set Up	06/06/96	09:00 AM	06/06/96	10:00 AM																		
29	Preincubation.	06/06/96	10:00 AM	06/06/96	11:00 AM																		
30	Fermentation	06/06/96	11:00 AM	06/07/96	08:00 AM		1									3				3			
31	CIP	06/07/96	08:00 AM	06/07/96	09:00 AM																		
32	SIP	06/07/96	09:00 AM	06/07/96	10:00 AM																		
33	Clean Up	06/07/96	10:00 AM	06/07/96	12:00 PM																		
34	Subtotal																						
35																							
36	5 A Heat Exchange																						
37																							
38	Set Up	06/07/96	08:00 AM	06/07/96	08:30 AM																		
39	Transfer	06/07/96	08:00 AM	06/07/96	09:00 AM																		
40	CIP	06/07/96	09:00 AM	06/07/96	10:00 AM																		
41	SIP	06/07/96	10:00 AM	06/07/96	11:00 AM																		
42	Clean Up	06/07/96	11:00 AM	06/07/96	01:00 PM																		
43	Subtotal																						
44																							
45	6 A Cont. Cent./Solids																						
46																							
47	Set Up	06/07/96	08:00 AM	06/07/96	09:00 AM																		

FIG. 45A

QC Load Table - PE Module

4506

	Operation	Start Date	Start Time	Finish Date	Finish Time	QA/QC Samples: Visual AV-1	Visual AV-2	Chemical AC-1	AC-2	AC-3	AC-4	AC-5	AC-6	Biochemical AB-1	AB-2	AB-3	AB-4	AB-5	AB-6	AB-7	Immulogical AI-1	AI-2	Act. AA-1
		06/03/96	08:00 AM													3		3			3		
48	Centrifugation	06/07/96	09:00 AM	06/07/96	10:00 AM																		
49	Wash	06/07/96	10:00 AM	06/07/96	10:06 AM																		
50	CIP	06/07/96	10:06 AM	06/07/96	10:21 AM																		
51	SIP	06/07/96	10:21 AM	06/07/96	11:21 AM																		
52	Clean Up	06/07/96	11:21 AM	06/07/96	11:51 AM																		
53	Sub Total																						
54																							
55	1 B Inoculum Prep																						
56																							
57	Set Up	06/03/96	01:30 PM	06/03/96	02:30 PM																		
58	Preincubation	06/03/96	02:30 PM	06/03/96	03:30 PM																		
59	Incubation	06/03/96	03:30 PM	06/04/96	02:30 PM																		
60	Clean Up	06/04/96	02:30 PM	06/04/96	02:45 PM																		
60	Subtotal																						
61																							
62	2 B Flask Growth																						
63																							
64	Set Up	06/04/96	12:30 PM	06/04/96	01:30 PM																		
65	Preincubation	06/04/96	01:30 PM	06/04/96	02:30 PM																		
66	Incubation	06/04/96	02:30 PM	06/05/96	01:30 PM																		
67	Clean Up	06/05/96	01:30 PM	06/05/96	01:45 PM																		
67	Subtotal																						
68																							
69	3 B Seed Fermentation																						
70																							
71	Set Up	06/05/96	11:30 AM	06/05/96	12:30 PM																		
72	Preincubation	06/05/96	12:30 PM	06/05/96	01:30 PM																		
73	Fermentation	06/05/96	01:30 PM	06/06/96	10:30 AM		2																
74	Harvest	06/06/96	10:30 AM	06/06/96	11:00 AM																		
75	CIP	06/06/96	10:30 AM	06/06/96	11:30 AM																		
76	SIP	06/06/96	11:30 AM	06/06/96	12:30 PM																		
77	Clean Up	06/06/96	12:30 PM	06/06/96	03:30 PM																		
78	Subtotal																						
79																							
80	4 B Production Fermentation																						
81																							
82	Set Up	06/06/96	09:00 AM	06/06/96	10:00 AM																		
83	Preincubation	06/06/96	10:00 AM	06/06/96	11:00 AM																		
84	Fermentation	06/06/96	11:00 AM	06/07/96	08:00 AM		2									3					3		
85	CIP	06/07/96	08:00 AM	06/07/96	09:00 AM																		
86	SIP	06/07/96	09:00 AM	06/07/96	10:00 AM																		
87	Clean Up	06/07/96	10:00 AM	06/07/96	12:00 PM																		
88	Subtotal																						
89																							
90	6 B Heat Exchange																						
91																							
92	Set Up	06/07/96	08:00 AM	06/07/96	08:30 AM																		
93	Transfer	06/07/96	08:00 AM	06/07/96	09:00 AM																		
94	CIP	06/07/96	09:00 AM	06/07/96	10:00 AM																		

FIG. 45B

QC Load Table - PE Module

	Operation	Start		Finish		QA/QC Samples																	
						Visual		Chemical						Biochemical							Immulogical		Act.
		Date	Time	Date	Time	AV-1	AV-2	AC-1	AC-2	AC-3	AC-4	AC-5	AC-6	AB-1	AB-2	AB-3	AB-4	AB-5	AB-6	AB-7	AI-1	AI-2	AA-1
		06/03/96	08:00 AM																				
95	SIP	06/07/96	10:00 AM	06/07/96	11:00 AM																		
96	Clean Up	06/07/96	11:00 AM	06/07/96	01:00 PM																		
97	Subtotal																						
98																							
99	6 B Cont. Cent./Solids																						
100																							
101	Set Up	06/07/96	08:00 AM	06/07/96	09:00 AM											3		3			3		
102	Centrifugation	06/07/96	09:00 AM	06/07/96	10:00 AM																		
103	Wash	06/07/96	10:00 AM	06/07/96	10:06 AM																		
104	CIP	06/07/96	10:06 AM	06/07/96	10:21 AM																		
105	SIP	06/07/96	10:21 AM	06/07/96	11:21 AM																		
106	Clean Up	06/07/96	11:21 AM	06/07/96	11:51 AM																		
107	Sub Total																						
108																							
109	1 C Inoculum Prep																						
110																							
111	Set Up	06/03/96	01:30 PM	06/03/96	02:30 PM																		
112	Preincubation	06/03/96	02:30 PM	06/03/96	03:30 PM																		
113	Incubation	06/03/96	03:30 PM	06/04/96	02:30 PM																		
114	Clean Up	06/04/96	02:30 PM	06/04/96	02:45 PM																		
115	Subtotal																						
116																							
117	2 C Flask Growth																						
118																							
119	Set Up	06/04/96	12:30 PM	06/04/96	01:30 PM																		
120	Preincubation	06/04/96	01:30 PM	06/04/96	02:30 PM																		
121	Incubation	06/04/96	02:30 PM	06/05/96	01:30 PM																		
121	Clean Up	06/05/96	01:30 PM	06/05/96	01:45 PM																		
122	Subtotal																						
123																							
124	3 C Seed Fermentation																						
125																							
126	Set Up	06/05/96	11:30 AM	06/05/96	12:30 PM																		
127	Preincubation	06/05/96	12:30 PM	06/05/96	01:30 PM																		
128	Fermentation	06/05/96	01:30 PM	06/06/96	10:30 AM		2																
129	Harvest	06/06/96	10:30 AM	06/06/96	11:00 AM																		
130	CIP	06/06/96	10:30 AM	06/06/96	11:30 AM																		
131	SIP	06/06/96	11:30 AM	06/06/96	12:30 PM																		
132	Clean Up	06/06/96	12:30 PM	06/06/96	03:30 PM																		
133	Subtotal																						
134																							
135	4 C Production Fermentation																						
136																							
137	Set Up	06/06/96	09:00 AM	06/06/96	10:00 AM																		
138	Preincubation	06/06/96	10:00 AM	06/06/96	11:00 AM																		
139	Fermentation	06/06/96	11:00 AM	06/07/96	08:00 AM		2									3					3		
140	CIP	06/07/96	08:00 AM	06/07/96	09:00 AM																		
141	SIP	06/07/96	09:00 AM	06/07/96	10:00 AM																		
	Clean Up	06/07/96	10:00 AM	06/07/96	12:00 PM																		

FIG. 45C

QC Load Table - PE Module

	Operation	Start		Finish		QA/QC Samples																	
						Visual		Chemical						Biochemical							Immulogical		Act.
		Date	Time	Date	Time	AV-1	AV-2	AC-1	AC-2	AC-3	AC-4	AC-5	AC-6	AB-1	AB-2	AB-3	AB-4	AB-5	AB-6	AB-7	AI-1	AI-2	AA-1
		06/03/96	08:00 AM																				
142	Subtotal																						
143																							
144	5 C Heat Exchange																						
145																							
146	Set Up	06/07/96	08:00 AM	06/07/96	08:30 AM																		
147	Transfer	06/07/96	08:00 AM	06/07/96	09:00 AM																		
148	CIP	06/07/96	09:00 AM	06/07/96	10:00 AM																		
149	SIP	06/07/96	10:00 AM	06/07/96	11:00 AM																		
150	Clean Up	06/07/96	11:00 AM	06/07/96	01:00 PM																		
151	Subtotal																						
152																							
153	6 C Cont. Cent./Solids																						
154																							
155	Set Up	06/07/96	08:00 AM	06/07/96	09:00 AM											3		3			3		
156	Centrifugation	06/07/96	09:00 AM	06/07/96	10:00 AM																		
157	Wash	06/07/96	10:00 AM	06/07/96	10:06 AM																		
158	CIP	06/07/96	10:06 AM	06/07/96	10:21 AM																		
159	SIP	06/07/96	10:21 AM	06/07/96	11:21 AM																		
160	Clean Up	06/07/96	11:21 AM	06/07/96	11:51 AM																		
161	Sub Total																						
162																							
163	7 A Resolubilization																						
164																							
165	Set Up	06/07/96	09:06 AM	06/07/96	10:06 AM																		
166	Dilution	06/07/96	10:06 AM	06/07/96	10:36 AM																		
167	Agitate	06/07/96	10:36 AM	06/07/96	11:36 AM																		
168	CIP	06/07/96	11:36 AM	06/07/96	12:36 PM																		
169	SIP	06/07/96	12:36 PM	06/07/96	01:36 PM																		
170	Clean Up	06/07/96	01:36 PM	06/07/96	02:36 PM																		
171	Subtotal																						
172																							
173	8 A Heat Exchange																						
174																							
175	Set Up	06/07/96	11:06 AM	06/07/96	11:36 AM																		
176	Transfer	06/07/96	11:36 AM	06/07/96	11:54 AM																		
177	CIP	06/07/96	11:54 AM	06/07/96	11:54 AM																		
178	SIP	06/07/96	11:54 AM	06/07/96	11:54 AM																		
179	Clean Up	06/07/96	11:54 AM	06/07/96	11:54 AM																		
180	Subtotal																						
181																							
182	9 A Hommogenization																						
183																							
184	Set Up	06/07/96	11:39 AM	06/07/96	11:54 AM																		
185	Lysis	06/07/96	11:54 AM	06/07/96	12:34 PM																		
186	CIP	06/07/96	12:34 PM	06/07/96	12:34 PM																		
187	SIP	06/07/96	12:34 PM	06/07/96	12:34 PM																		
188	Clean Up	06/07/96	12:34 PM	06/07/96	12:34 PM																		
189	Sub Total																						
190																							

FIG. 45D

QC Load Table - PE Module

	Operation	Start		Finish		QA/QC Samples																	
						Visual		Chemical						Biochemical							Immulogical		Act.
		Date	Time	Date	Time	AV-1	AV-2	AC-1	AC-2	AC-3	AC-4	AC-5	AC-6	AB-1	AB-2	AB-3	AB-4	AB-5	AB-6	AB-7	AI-1	AI-2	AA-1
		06/03/96	08:00 AM																				
191	10 A Heat Exchange																						
192																							
193	Set Up	06/07/96	12:04 PM	06/07/96	12:34 PM																		
194	Transfer	06/07/96	12:34 PM	06/07/96	12:52 PM																		
195	CIP	06/07/96	12:52 PM	06/07/96	12:52 PM																		
196	SIP	06/07/96	12:52 PM	06/07/96	12:52 PM																		
197	Clean Up	06/07/96	12:52 PM	06/07/96	12:52 PM																		
198	Subtotal																						
199																							
200	8 B Heat Exchange																						
201																							
202	Set Up	06/07/96	12:52 PM	06/07/96	12:52 PM																		
203	Transfer	06/07/96	12:52 PM	06/07/96	01:10 PM																		
204	CIP	06/07/96	01:10 PM	06/07/96	01:10 PM																		
205	SIP	06/07/96	01:10 PM	06/07/96	01:10 PM																		
206	Clean Up	06/07/96	01:10 PM	06/07/96	01:10 PM																		
207	Subtotal																						
208																							
209	9 B Hommogenization																						
210																							
211	Set Up	06/07/96	01:10 PM	06/07/96	01:10 PM																		
212	Lysis	06/07/96	01:10 PM	06/07/96	01:51 PM																		
213	CIP	06/07/96	01:51 PM	06/07/96	01:51 PM																		
214	SIP	06/07/96	01:51 PM	06/07/96	01:51 PM																		
215	Clean Up	06/07/96	01:51 PM	06/07/96	01:51 PM																		
216	Sub Total																						
217																							
218	10 B Heat Exchange																						
219																							
220	Set Up	06/07/96	01:21 PM	06/07/96	01:51 PM																		
221	Transfer	06/07/96	01:51 PM	06/07/96	02:09 PM																		
222	CIP	06/07/96	02:09 PM	06/07/96	02:09 PM																		
223	SIP	06/07/96	02:09 PM	06/07/96	02:09 PM																		
224	Clean Up	06/07/96	02:09 PM	06/07/96	02:09 PM																		
225	Subtotal																						
226																							
227	8 C Heat Exchange																						
228																							
229	Set Up	06/07/96	02:09 PM	06/07/96	02:09 PM																		
230	Transfer	06/07/96	02:09 PM	06/07/96	02:27 PM																		
231	CIP	06/07/96	02:27 PM	06/07/96	03:27 PM																		
232	SIP	06/07/96	03:27 PM	06/07/96	04:27 PM																		
233	Clean Up	06/07/96	04:27 PM	06/07/96	05:27 PM																		
234	Subtotal																						
235																							
236	9 C Hommogenization																						
237																							
238	Set Up	06/07/96	02:27 PM	06/07/96	02:27 PM																		
239	Lysis	06/07/96	02:27 PM	06/07/96	03:07 PM																		

FIG. 45E

QC Load Table - PE Module

	Operation	Start		Finish		QA/QC Samples																	
						Visual		Chemical						Biochemical							Immulogical		Act.
		Date	Time	Date	Time	AV-1	AV-2	AC-1	AC-2	AC-3	AC-4	AC-5	AC-6	AB-1	AB-2	AB-3	AB-4	AB-5	AB-6	AB-7	AI-1	AI-2	AA-1
		06/03/96	08:00 AM																				
240	CIP	06/07/96	03:07 PM	06/07/96	04:07 PM																		
241	SIP	06/07/96	04:07 PM	06/07/96	05:07 PM																		
242	Clean Up	06/07/96	05:07 PM	06/07/96	06:07 PM																		
243	Sub Total																						
244																							
245	10 C Heat Exchange																						
246																							
247	Set Up	06/07/96	03:07 PM	06/07/96	03:07 PM																		
248	Transfer	06/07/96	03:07 PM	06/07/96	03:25 PM																		
249	CIP	06/07/96	03:25 PM	06/07/96	04:25 PM																		
250	SIP	06/07/96	04:25 PM	06/07/96	05:25 PM																		
251	Clean Up	06/07/96	05:25 PM	06/07/96	06:25 PM																		
252	Subtotal																						
253																							
254	11 A Resolubilization																						
255																							
256	Set Up	06/07/96	11:52 AM	06/07/96	12:52 PM																		
257	Dilution	06/07/96	12:52 PM	06/07/96	01:22 PM																		
258	Agitate	06/07/96	01:22 PM	06/07/96	01:52 PM																		
259	CIP	06/07/96	01:52 PM	06/07/96	01:52 PM																		
260	SIP	06/07/96	01:52 PM	06/07/96	01:52 PM																		
261	Clean Up	06/07/96	01:52 PM	06/07/96	01:52 PM																		
262	Subtotal																						
263																							
264	12 A Cont. Cent./Solids																						
265																							
266	Set Up	06/07/96	12:52 PM	06/07/96	01:52 PM																		
267	Centrifugation	06/07/96	01:52 PM	06/07/96	02:22 PM																		
268	Wash	06/07/96	02:22 PM	06/07/96	02:28 PM																		
269	CIP	06/07/96	02:28 PM	06/07/96	02:28 PM																		
270	SIP	06/07/96	02:28 PM	06/07/96	02:28 PM																		
271	Clean Up	06/07/96	02:28 PM	06/07/96	02:28 PM																		
272	Sub Total																						
273																							
274	11 B Resolubilization																						
275																							
276	Set Up	06/07/96	02:28 PM	06/07/96	02:28 PM																		
277	Dilution	06/07/96	02:28 PM	06/07/96	02:58 PM																		
278	Agitate	06/07/96	02:58 PM	06/07/96	03:13 PM																		
279	CIP	06/07/96	03:13 PM	06/07/96	04:13 PM																		
280	SIP	06/07/96	04:13 PM	06/07/96	05:13 PM																		
281	Clean Up	06/07/96	05:13 PM	06/07/96	06:13 PM																		
282	Subtotal																						
283																							
284	12 B Cont. Cent./Solids																						
285																							
286	Set Up	06/07/96	02:13 PM	06/07/96	03:13 PM																		
287	Centrifugation	06/07/96	03:13 PM	06/07/96	03:43 PM																		
288	Wash	06/07/96	03:43 PM	06/07/96	03:49 PM																		

FIG. 45F

QC Load Table - PE Module

	Operation	Start		Finish		QA/QC Samples																	
						Visual		Chemical						Biochemical							Immulogical		Act.
		Date	Time	Date	Time	AV-1	AV-2	AC-1	AC-2	AC-3	AC-4	AC-5	AC-6	AB-1	AB-2	AB-3	AB-4	AB-5	AB-6	AB-7	AI-1	AI-2	AA-1
		06/03/96	08:00 AM																				
289	CIP	06/07/96	03:49 PM	06/07/96	04:04 PM																		
290	SIP	06/07/96	04:04 PM	06/07/96	05:04 PM																		
291	Clean Up	06/07/96	05:04 PM	06/07/96	05:34 PM																		
292	Sub Total																						
293																							
294	13 A Resolubilization																						
295																							
296	Set Up	06/07/96	01:28 PM	06/07/96	02:28 PM																		
297	Dilution	06/07/96	02:28 PM	06/07/96	02:58 PM																		
298	Agitate	06/07/96	02:58 PM	06/08/96	08:58 AM																		
299	CIP	06/08/96	08:58 AM	06/08/96	09:58 AM																		
300	SIP	06/08/96	09:58 AM	06/08/96	10:58 AM																		
301	Clean Up	06/08/96	10:58 AM	06/08/96	11:58 AM																		
302	Subtotal																						
303																							
304	14 A Concentration																						
305																							
306	Set Up	06/08/96	06:38 AM	06/08/96	07:38 AM																		
307	Flush	06/08/96	07:38 AM	06/08/96	08:18 AM																		
308	Prime	06/08/96	08:18 AM	06/08/96	08:58 AM																		
309	Concentration	06/08/96	08:58 AM	06/08/96	09:58 AM																		
310	Dilution	06/08/96	09:58 AM	06/08/96	10:25 AM																		
311	Wash	06/08/96	10:25 AM	06/08/96	11:19 AM																		
312	Flush	06/08/96	11:19 AM	06/08/96	11:39 AM																		
313	Store	06/08/96	11:39 AM	06/08/96	12:19 PM																		
314	CIP	06/08/96	12:19 PM	06/08/96	01:19 PM																		
315	SIP	06/08/96	01:19 PM	06/08/96	02:19 PM																		
316	Clean Up	06/08/96	02:19 PM	06/08/96	03:19 PM																		
317	Sub Total																						
318																							
319	15 A Microfiltration																						
320																							
321	Set Up	06/08/96	10:03 AM	06/08/96	11:03 AM																		
322	Flush	06/08/96	11:03 AM	06/08/96	11:11 AM																		
323	Prime	06/08/96	11:11 AM	06/08/96	11:19 AM																		
324	Filtration	06/08/96	11:19 AM	06/08/96	11:49 AM																		
325	Wash	06/08/96	11:49 AM	06/08/96	11:49 AM																		
326	Regenerate	06/08/96	11:49 AM	06/08/96	11:51 AM																		
327	Store	06/08/96	11:51 AM	06/08/96	11:55 AM																		
328	CIP	06/08/96	11:55 AM	06/08/96	12:55 PM																		
329	SIP	06/08/96	12:55 PM	06/08/96	01:55 PM																		
330	Clean Up	06/08/96	01:55 PM	06/08/96	02:55 PM																		
331	Sub Total																						
332																							
333	16 A P/A MPLC																						
334																							
335	Equilibration	06/08/96	10:17 AM	06/08/96	11:24 AM																		
336	Load	06/08/96	11:49 AM	06/08/96	12:31 PM																		
337	Wash	06/08/96	12:31 PM	06/08/96	01:52 PM																		

FIG. 45G

QC Load Table - PE Module

	Operation	Start		Finish		QA/QC Samples																	
						Visual		Chemical						Biochemical							Immulogical		Act.
		Date	Time	Date	Time	AV-1	AV-2	AC-1	AC-2	AC-3	AC-4	AC-5	AC-6	AB-1	AB-2	AB-3	AB-4	AB-5	AB-6	AB-7	AI-1	AI-2	AA-1
		06/03/96	08:00 AM																				
338	Elute A	06/08/96	01:52 PM	06/08/96	03:12 PM																		
339	Elute B	06/08/96	03:12 PM	06/08/96	03:12 PM																		
340	Regenerate	06/08/96	03:12 PM	06/08/96	03:25 PM																		
341	Store	06/08/96	03:25 PM	06/08/96	03:52 PM																		
342	CIP	06/08/96	03:52 PM	06/08/96	04:52 PM																		
343	SIP	06/08/96	04:52 PM	06/08/96	05:52 PM																		
344	Clean Up	06/08/96	05:52 PM	06/08/96	06:52 PM																		
345	Sub Total																						
346																							
347																							
348	17 A P/A MPLC																						
349																							
350	Equilibration	06/08/96	02:59 PM	06/08/96	03:38 PM																		
351	Load	06/08/96	03:12 PM	06/08/96	04:17 PM																		
352	Wash	06/08/96	04:17 PM	06/08/96	05:03 PM																		
353	Elute A	06/08/96	05:03 PM	06/08/96	05:49 PM																		
354	Elute B	06/08/96	05:49 PM	06/08/96	05:49 PM																		
355	Regenerate	06/08/96	05:49 PM	06/08/96	05:57 PM																		
356	Store	06/08/96	05:57 PM	06/08/96	06:13 PM																		
357	CIP	06/08/96	06:13 PM	06/08/96	07:13 PM																		
358	SIP	06/08/96	07:13 PM	06/08/96	08:13 PM																		
359	Clean Up	06/08/96	08:13 PM	06/08/96	09:13 PM																		
360	Sub Total																						
361																							
362	18 A Flow Dialysis																						
363																							
364	Set Up	06/08/96	03:29 PM	06/08/96	04:29 PM																		
365	Flush	06/08/96	04:29 PM	06/08/96	05:09 PM																		
366	Prime	06/08/96	05:09 PM	06/08/96	05:49 PM																		
367	Dialysis	06/08/96	05:49 PM	06/08/96	06:49 PM																		
368	Wash	06/08/96	06:49 PM	06/08/96	06:49 PM																		
369	Flush	06/08/96	06:49 PM	06/08/96	07:09 PM																		
370	Store	06/08/96	07:09 PM	06/08/96	07:49 PM																		
371	CIP	06/08/96	07:49 PM	06/08/96	08:49 PM																		
372	SIP	06/08/96	08:49 PM	06/08/96	09:49 PM																		
373	Clean Up	06/08/96	09:49 PM	06/08/96	10:49 PM																		
374	Sub Total																						
375																							
376	19 A P/A MPLC																						
377																							
378	Equilibration	06/08/96	05:59 PM	06/08/96	06:31 PM																		
379	Load	06/08/96	06:49 PM	06/08/96	07:03 PM																		
380	Wash	06/08/96	07:03 PM	06/08/96	07:41 PM																		
381	Elute A	06/08/96	07:41 PM	06/08/96	08:20 PM																		
382	Elute B	06/08/96	08:20 PM	06/08/96	08:20 PM																		
383	Regenerate	06/08/96	08:20 PM	06/08/96	08:26 PM																		
384	Store	06/08/96	08:26 PM	06/08/96	08:39 PM																		
385	CIP	06/08/96	08:39 PM	06/08/96	09:39 PM																		
386	SIP	06/08/96	09:39 PM	06/08/96	10:39 PM																		

FIG. 45H

QC Load Table - PE Module

	Operation	Start		Finish		QA/QC Samples																	
						Visual		Chemical						Biochemical							Immunological		Act.
		Date	Time	Date	Time	AV-1	AV-2	AC-1	AC-2	AC-3	AC-4	AC-5	AC-6	AB-1	AB-2	AB-3	AB-4	AB-5	AB-6	AB-7	AI-1	AI-2	AA-1
		06/03/96	08:00 AM																				
387	Clean Up	06/08/96	10:39 PM	06/08/96	11:39 PM																		
388	Sub Total																						
389																							
390	20 A Flow Dialysis																						
391																							
392	Set Up	06/08/96	07:00 PM	06/08/96	07:00 PM																		
393	Flush	06/08/96	07:00 PM	06/08/96	07:40 PM																		
394	Prime	06/08/96	07:40 PM	06/08/96	08:20 PM																		
395	Dialysis	06/08/96	08:20 PM	06/08/96	10:20 PM																		
396	Wash	06/08/96	10:20 PM	06/08/96	10:20 PM																		
397	Flush	06/08/96	10:20 PM	06/08/96	10:40 PM																		
398	Store	06/08/96	10:40 PM	06/08/96	11:20 PM																		
399	CIP	06/08/96	11:20 PM	06/08/96	11:20 PM																		
400	SIP	06/08/96	11:20 PM	06/08/96	11:20 PM																		
401	Clean Up	06/08/96	11:20 PM	06/09/96	12:20 AM																		
402	Sub Total																						
403																							
404	21 A P/A MPLC																						
405																							
406	Equilibration	06/08/96	09:28 PM	06/08/96	09:57 PM																		
407	Load	06/08/96	10:20 PM	06/08/96	10:26 PM																		
408	Wash	06/08/96	10:26 PM	06/08/96	11:01 PM																		
409	Elute A	06/08/96	11:01 PM	06/08/96	11:36 PM																		
410	Elute B	06/08/96	11:36 PM	06/08/96	11:36 PM																		
411	Regenerate	06/08/96	11:36 PM	06/08/96	11:42 PM																		
412	Store	06/08/96	11:42 PM	06/08/96	11:54 PM																		
413	CIP	06/08/96	11:54 PM	06/08/96	11:54 PM																		
414	SIP	06/08/96	11:54 PM	06/08/96	11:54 PM																		
415	Clean Up	06/08/96	11:54 PM	06/09/96	12:54 AM																		
416	Sub Total																						
417																							
418	22 A Sterile Filtration																						
419																							
420	Set Up	06/09/96	08:06 AM	06/09/96	08:36 AM																		
421	Filtration	06/08/96	11:36 PM	06/09/96	12:06 AM																		
422	Storage	06/09/96	12:06 AM	06/09/96	12:36 AM																		
423	CIP	06/09/96	12:36 AM	06/09/96	12:36 AM																		
424	SIP	06/09/96	12:36 AM	06/09/96	12:36 AM																		
425	Clean Up	06/09/96	12:36 AM	06/09/96	01:36 AM																		
426	Sub Total																						

FIG. 45I

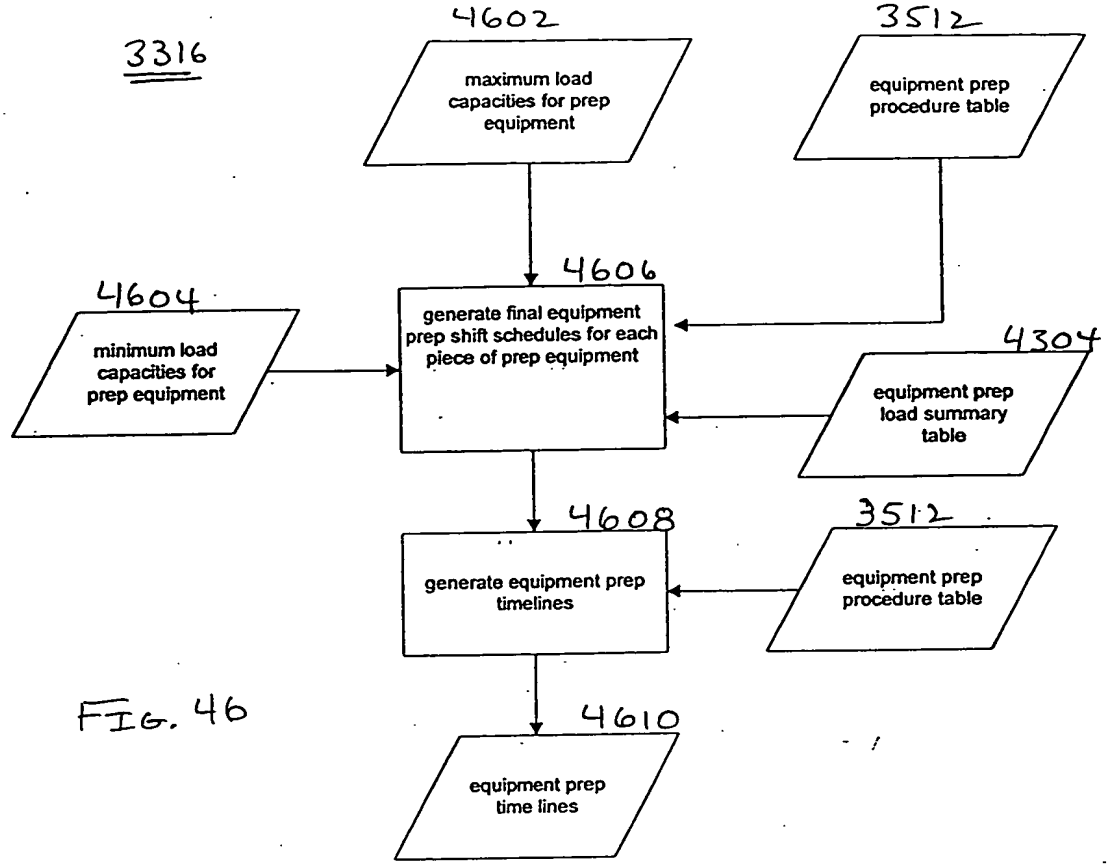

3316
4602
maximum load capacities for prep equipment
3512
equipment prep procedure table
4606
generate final equipment prep shift schedules for each piece of prep equipment
4604
minimum load capacities for prep equipment
4304
equipment prep load summary table
4608
generate equipment prep timelines
3512
equipment prep procedure table
4610
equipment prep time lines

FIG. 46

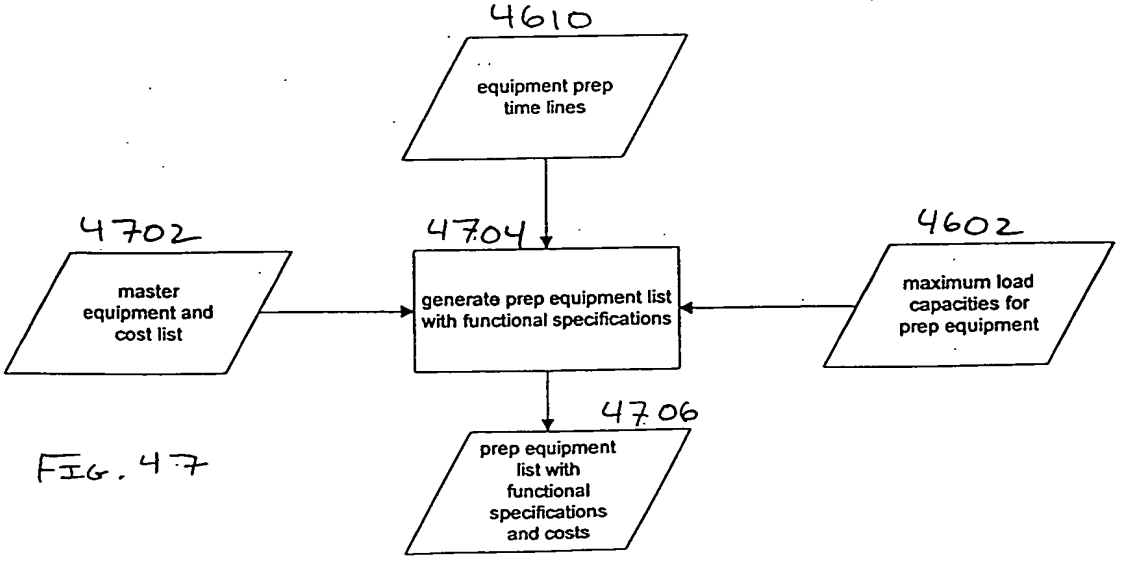

4610
equipment prep time lines
4702
master equipment and cost list
4704
generate prep equipment list with functional specifications
4602
maximum load capacities for prep equipment
4706
prep equipment list with functional specifications and costs

FIG. 47

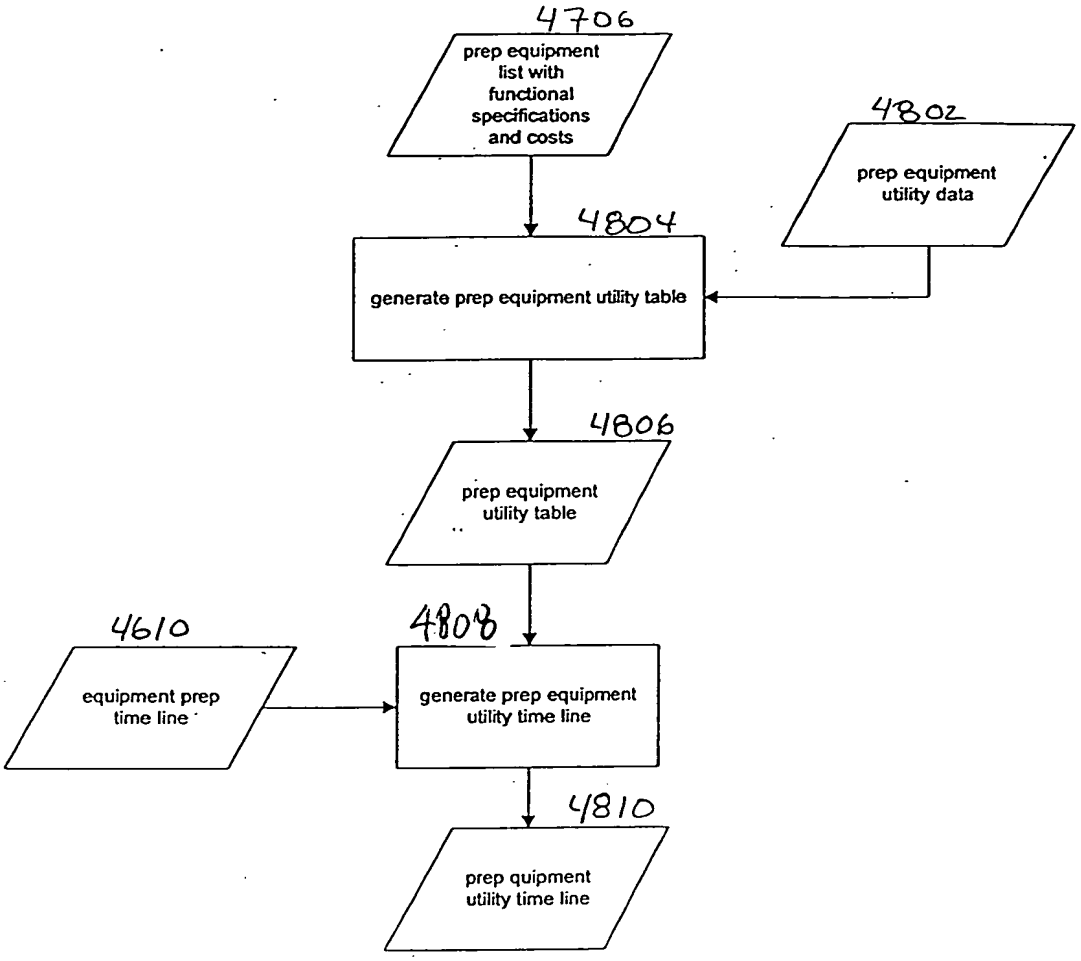

4706
prep equipment list with functional specifications and costs
4802
prep equipment utility data
4804
generate prep equipment utility table
4806
prep equipment utility table
4610
equipment prep time line
4808
generate prep equipment utility time line
4810
prep quipment utility time line

FIG. 48

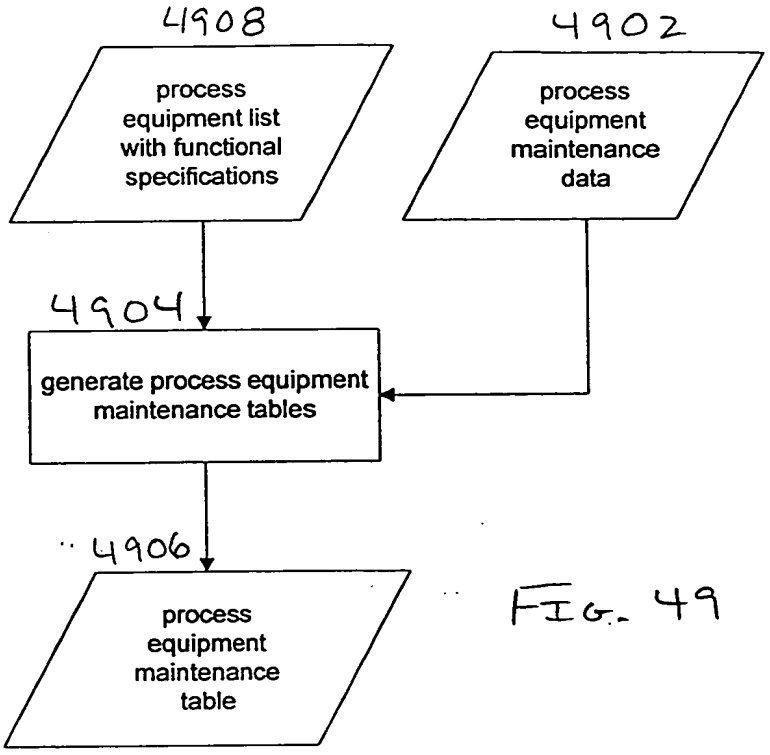

4908
process equipment list with functional specifications
4902
process equipment maintenance data
4904
generate process equipment maintenance tables
4906
process equipment maintenance table

FIG. 49

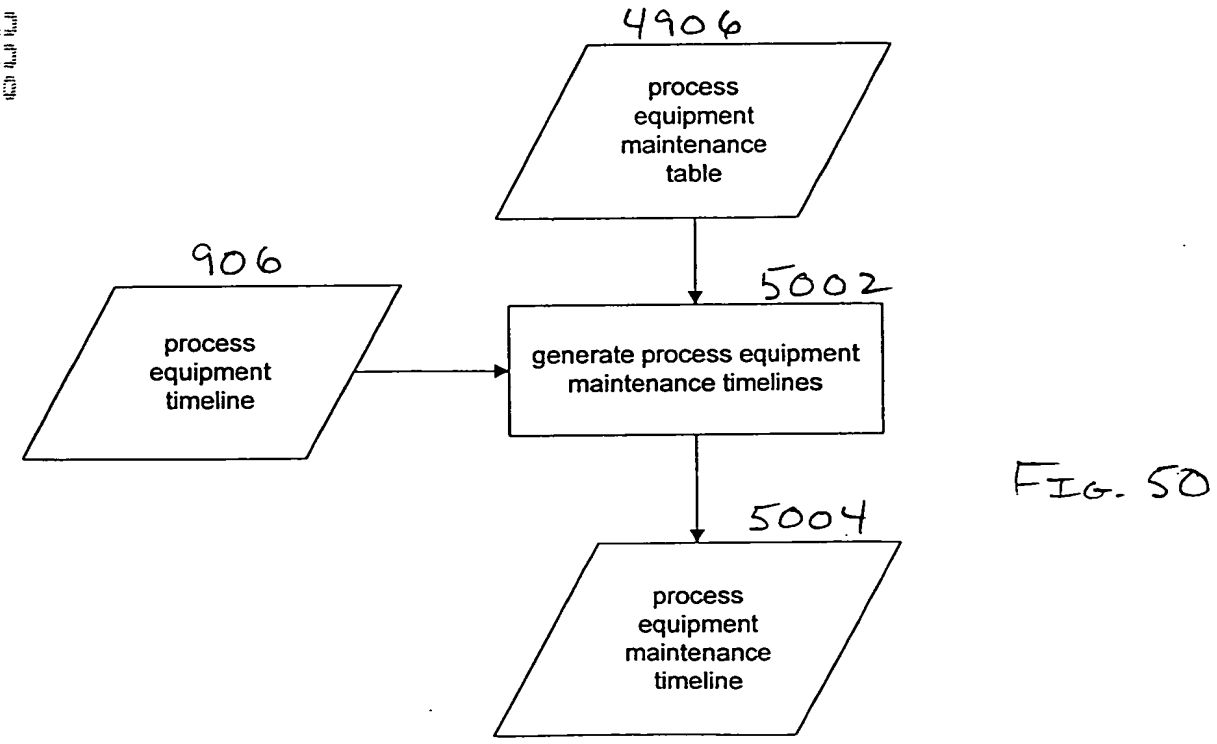

4906
process equipment maintenance table
906
process equipment timeline
5002
generate process equipment maintenance timelines
5004
process equipment maintenance timeline

FIG. 50

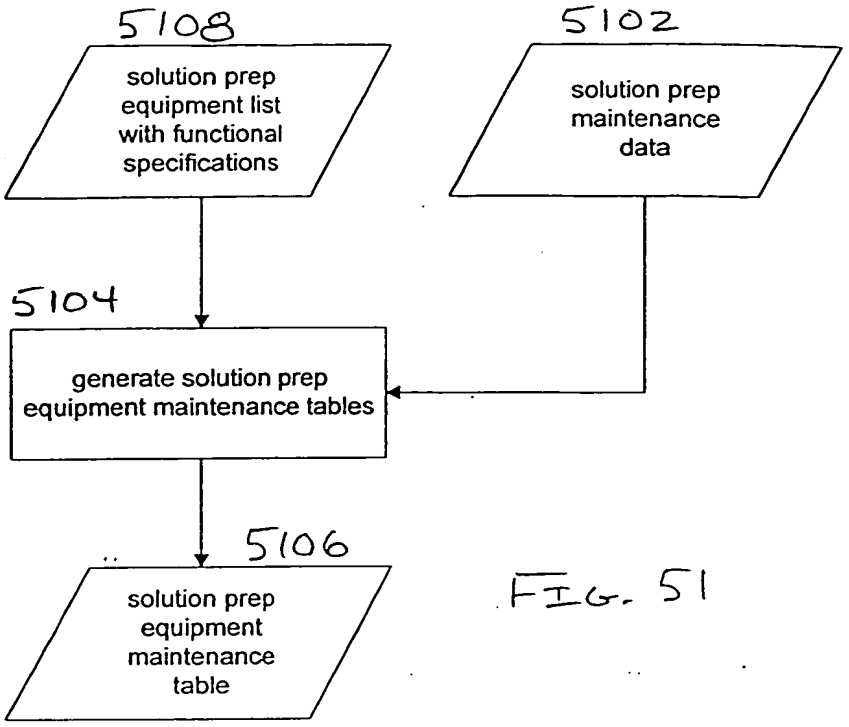

5108
solution prep equipment list with functional specifications
5102
solution prep maintenance data
5104
generate solution prep equipment maintenance tables
5106
solution prep equipment maintenance table

FIG. 51

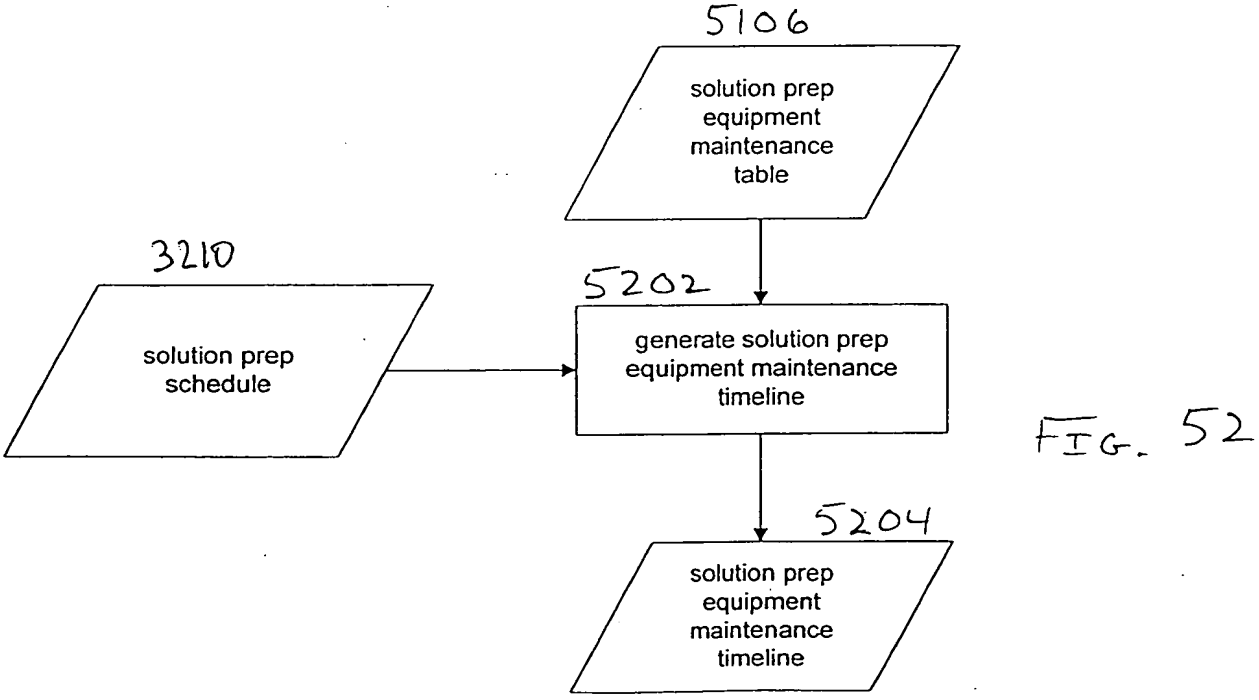

5106
solution prep equipment maintenance table
3210
solution prep schedule
5202
generate solution prep equipment maintenance timeline
5204
solution prep equipment maintenance timeline

FIG. 52

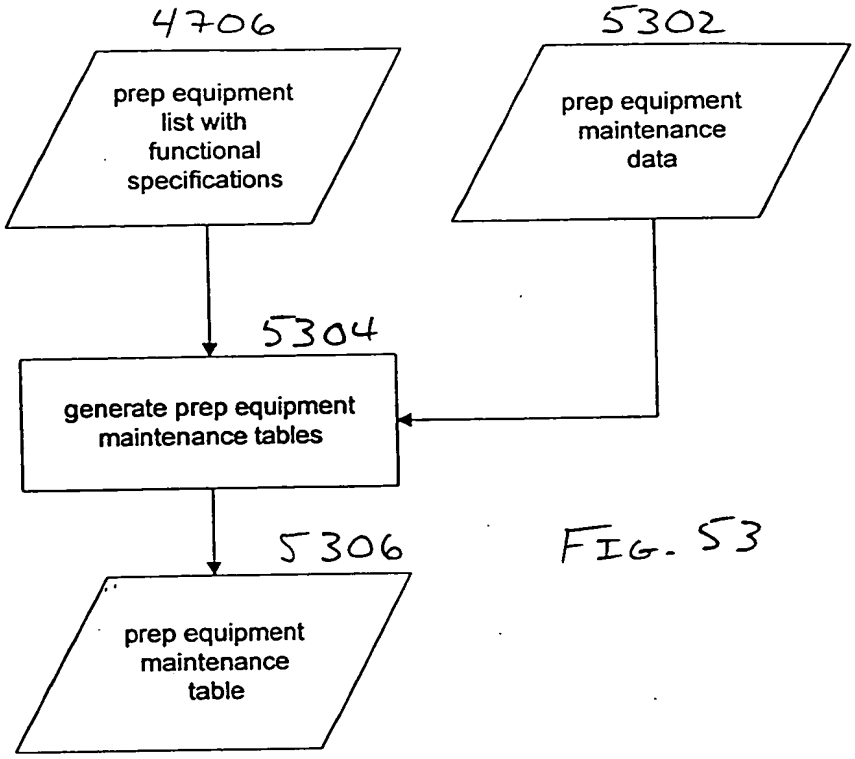

4706
prep equipment list with functional specifications
5302
prep equipment maintenance data
5304
generate prep equipment maintenance tables
5306
prep equipment maintenance table

FIG. 53

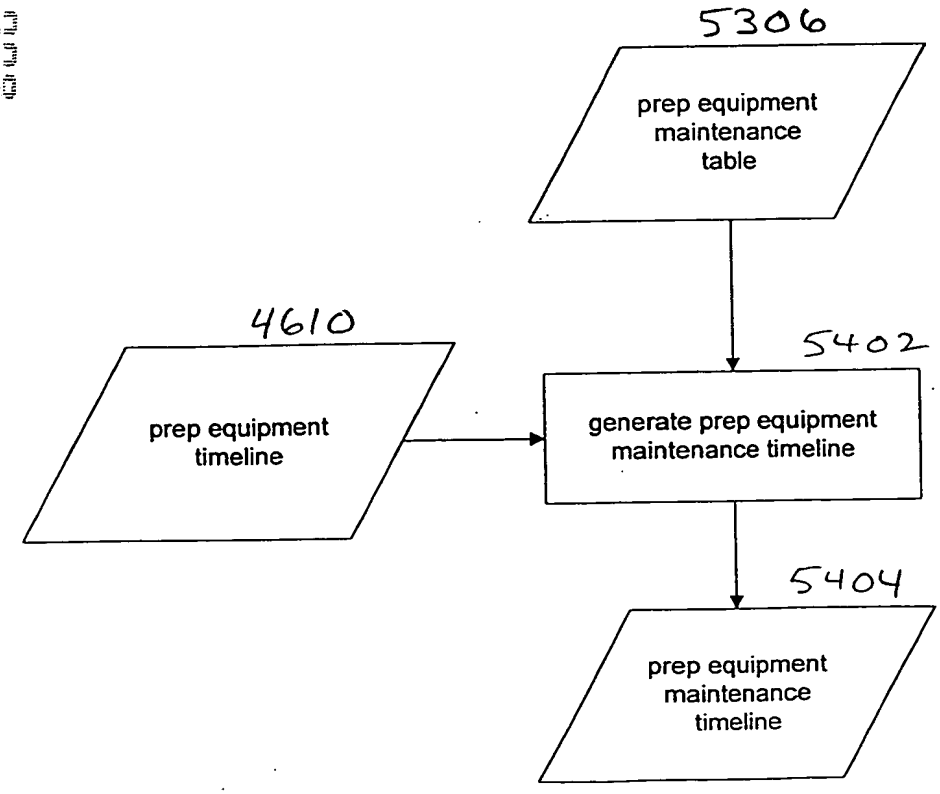

5306
prep equipment maintenance table
4610
prep equipment timeline
5402
generate prep equipment maintenance timeline
5404
prep equipment maintenance timeline

FIG. 54

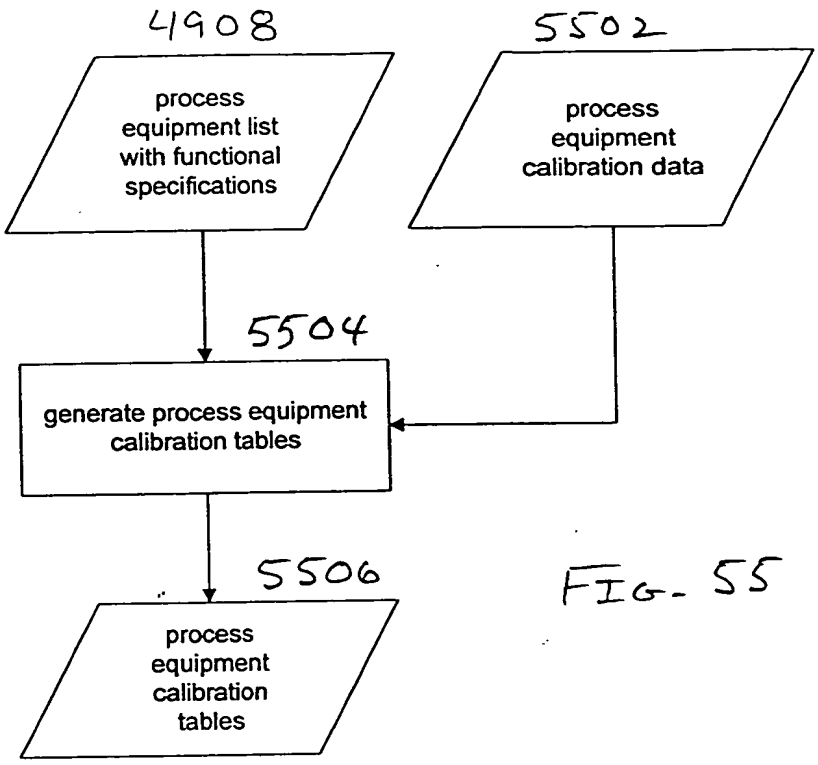

4908
process equipment list with functional specifications
5502
process equipment calibration data
5504
generate process equipment calibration tables
5506
process equipment calibration tables

FIG. 55

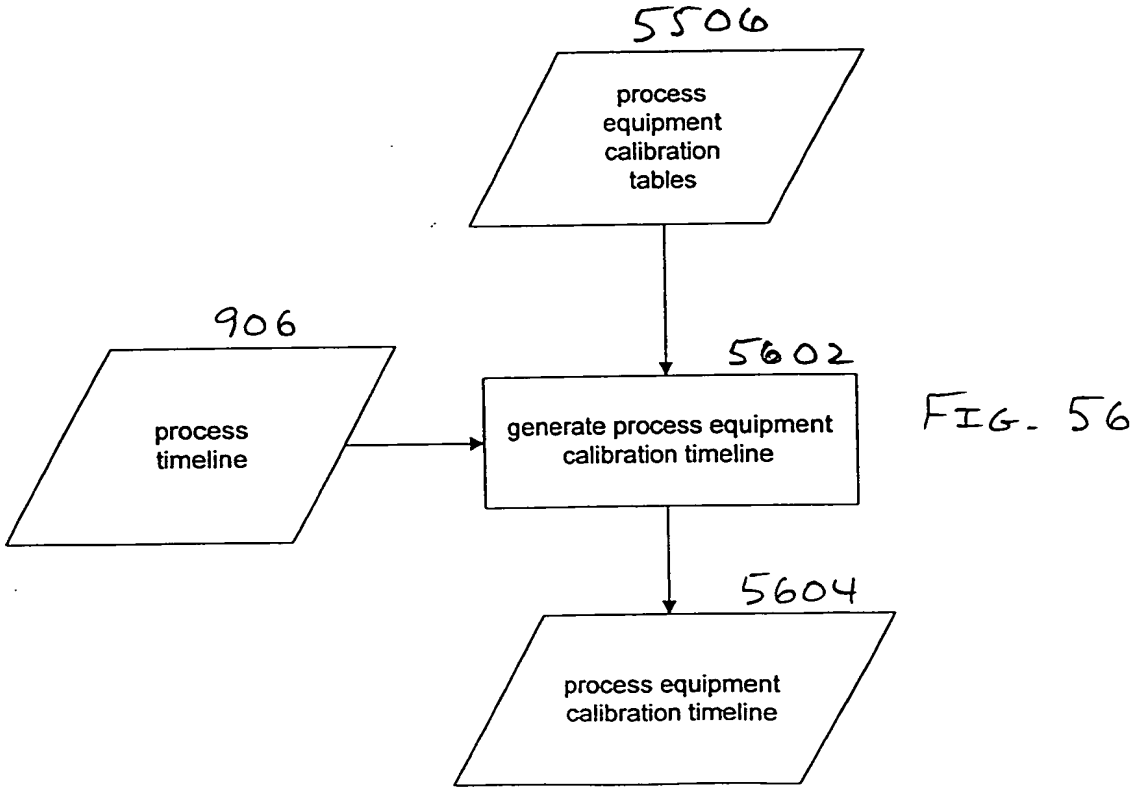

5506
process equipment calibration tables
906
process timeline
5602
generate process equipment calibration timeline
5604
process equipment calibration timeline

FIG. 56

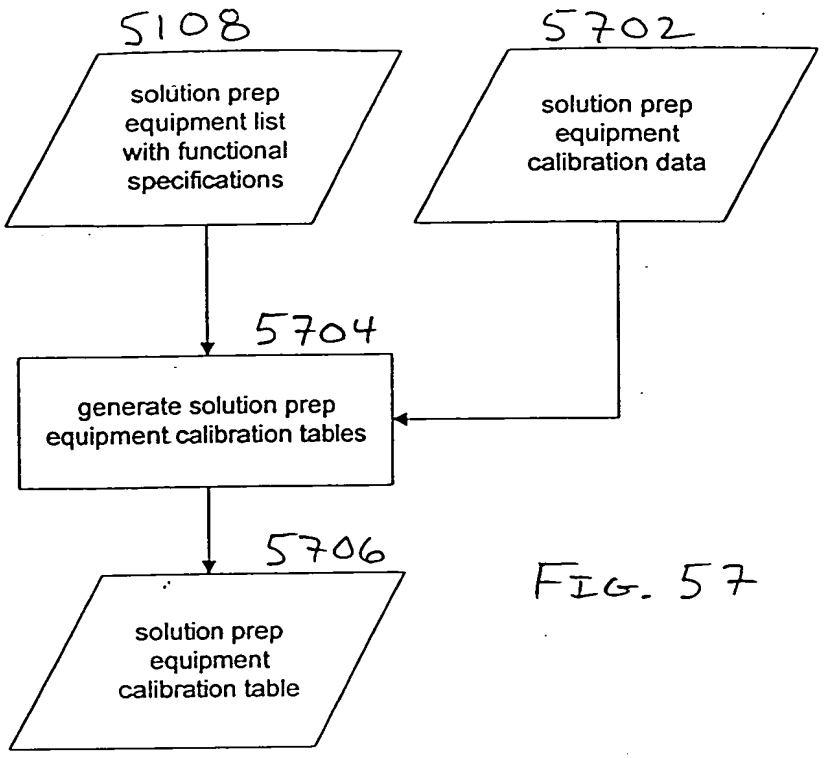

5108
solution prep equipment list with functional specifications
5702
solution prep equipment calibration data
5704
generate solution prep equipment calibration tables
5706
solution prep equipment calibration table

FIG. 57

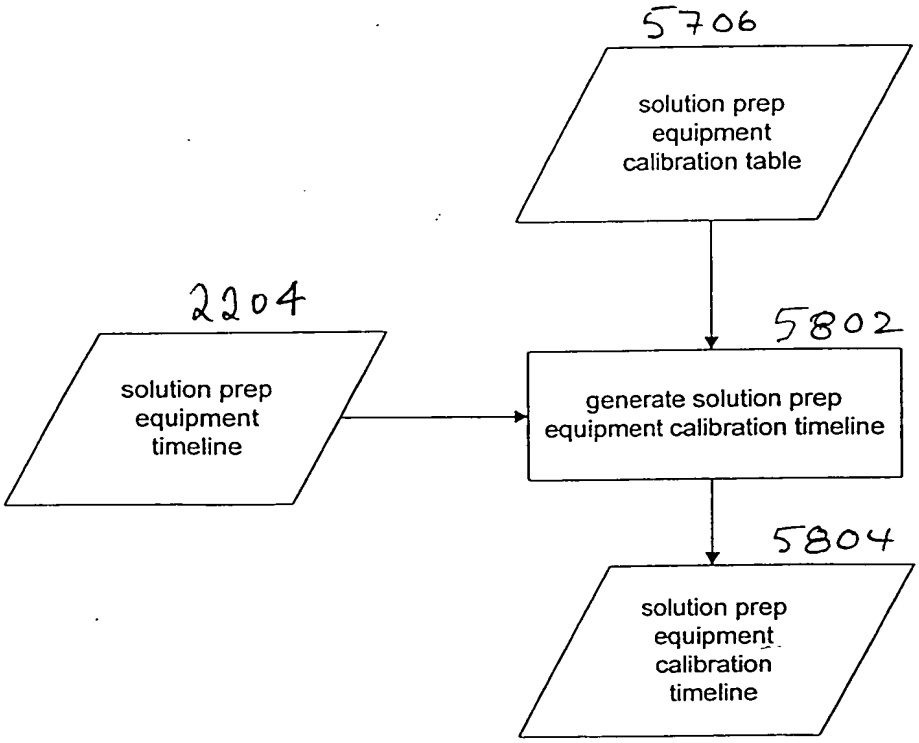

5706
solution prep equipment calibration table
2204
solution prep equipment timeline
5802
generate solution prep equipment calibration timeline
5804
solution prep equipment calibration timeline

FIG. 58

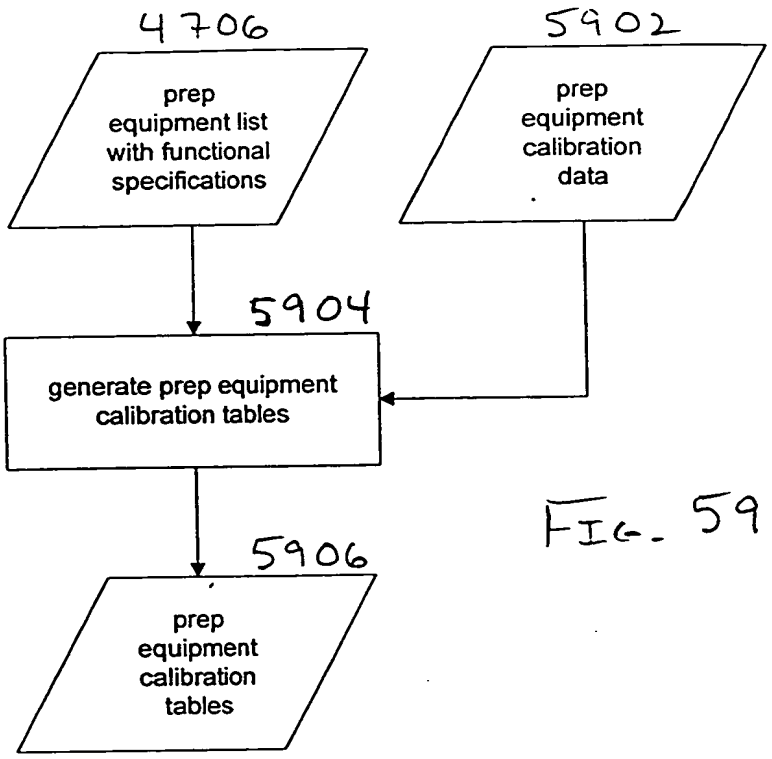

4706
prep equipment list with functional specifications
5902
prep equipment calibration data
5904
generate prep equipment calibration tables
5906
prep equipment calibration tables

FIG. 59

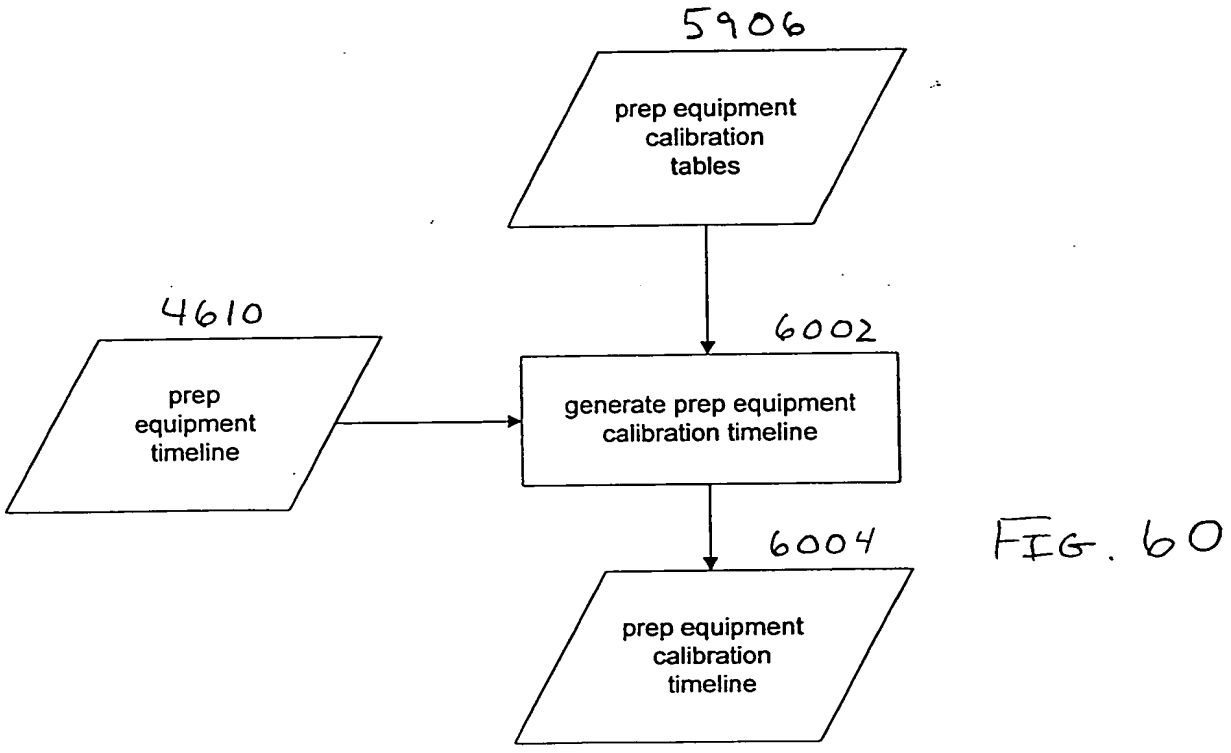

5906
prep equipment calibration tables
4610
prep equipment timeline
6002
generate prep equipment calibration timeline
6004
prep equipment calibration timeline

FIG. 60

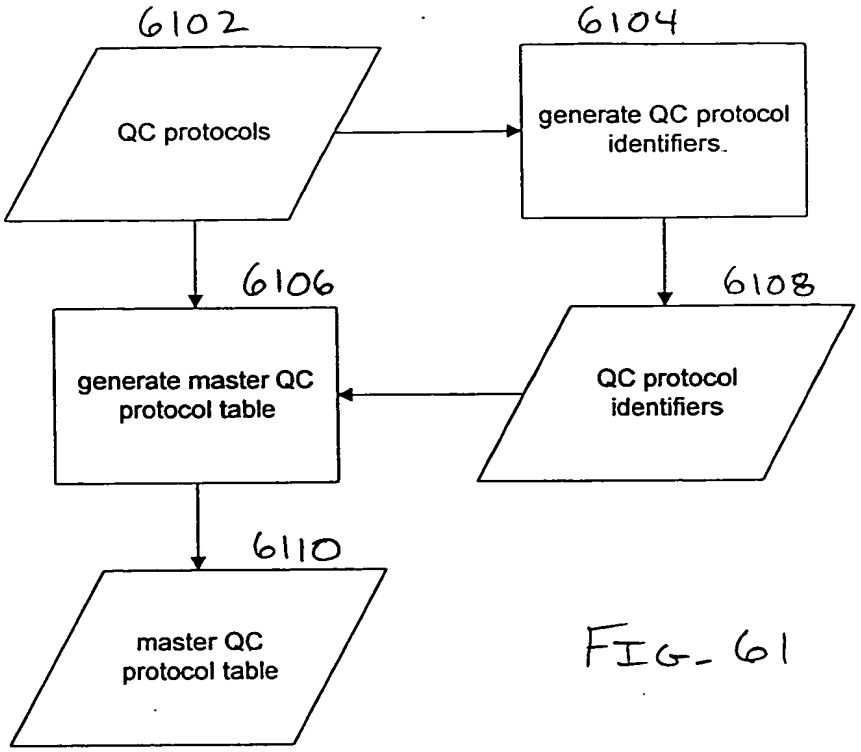

6102
QC protocols
6104
generate QC protocol identifiers.
6106
generate master QC protocol table
6108
QC protocol identifiers
6110
master QC protocol table

FIG. 61

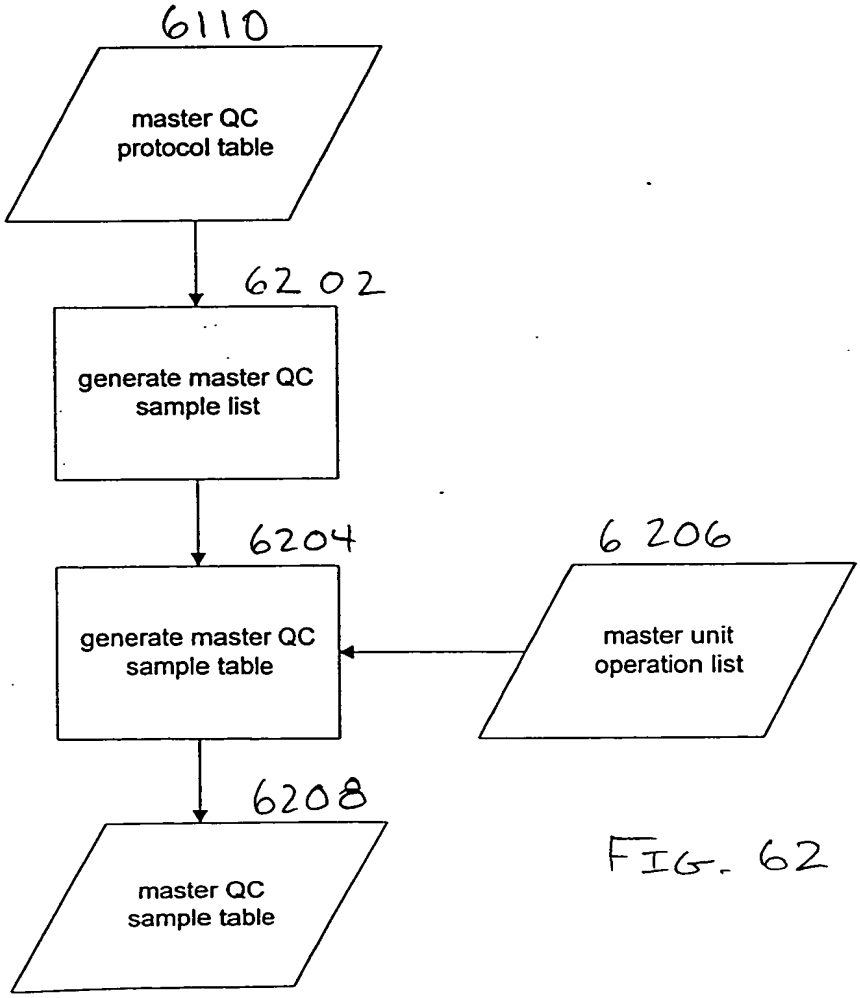

6110
master QC protocol table
6202
generate master QC sample list
6204
generate master QC sample table
6206
master unit operation list
6208
master QC sample table

FIG. 62

Equipment Maintenace Table - Microbial Fermentation

6402 6404 6406 6408

Equipment Items	Filters							Gaskets							Bearings
	Materials					Labor		Materials					Labor		Materials
	Item No.	Qty	Cycle Life	Unit Cost	$/Cycle	Hours	$/Cycle	Item No.	Qty	Cycle Life	Unit Cost	$/Cycle	Hours	$/Cycle	Item No.
#1 Inoculum Prep															
-80 C Stock Freezer															
Shaking Water Bath															
#2 Flask Growth															
Floor Incubator-Shaker															
Microscope															
#3 Seed Fermentation															
Seed Bioreactor															
#4 Fermentation															
Production Bioreactor	75868	1	100	55	.55	.5	.0875	48994	1	500	55	.11	1	.035	
#5 Whole Cell Harvest															
Harvest Heat Exchanger								62589	1	350	85	.2429	1	.05	
Harvest Vessel															
Agitator															
#6 Cell Concentration															
Pump															
Filter Holder															
Manifolding															
Instrumentation															
MF Flush Vessel															
MF Prime Vessel															
MF Filtrate Vessel															
Agitator															
MF Wash Vessel															
MF Regeneration Vessel															
MF Storage Vessel															

FIG. 64A

Equipment Maintenace Table - Microbial Fermentation

6408 6410 6412

Equipment Items							Seals							Belts	
					Labor		Materials					Labor		Materials	
	Qty	Cycle Life	Unit Cost	$/Cycle	Hours	$/Cycle	Item No.	Qty	Cycle Life	Unit Cost	$/Cycle	Hours	$/Cycle	Item No.	Qty
#1 Inoculum Prep															
-80 C Stock Freezer															
Shaking Water Bath															
#2 Flask Growth															
Floor Incubator-Shaker															
Microscope															
#3 Seed Fermentation															
Seed Bioreactor							54812 48695	2 1	250 250	12 18.9	.048 .0756	1 1	.07 .07		
#4 Fermentation															
Production Bioreactor														85258	1
#5 Whole Cell Harvest															
Harvest Heat Exchanger															
Harvest Vessel															
Agitator															
#6 Cell Concentration															
Pump															
Filter Holder															
Manifolding															
Instrumentation															
MF Flush Vessel															
MF Prime Vessel															
MF Filtrate Vessel															
Agitator															
MF Wash Vessel															
MF Regeneration Vessel															
MF Storage Vessel															

FIG. 64B

Equipment Maintenace Table - Microbial Fermentation

6414 6416 6418

Equipment Items						Shafts							Lubricant		
				Labor		Materials					Labor		Materials		
	Cycle Life	Unit Cost	$/Cycle	Hours	$/Cycle	Item No.	Qty	Cycle Life	Unit Cost	$/Cycle	Hours	$/Cycle	Item No.	Qty	Cycle Life
1 Inoculum Prep															
-80 C Stock Freezer															
Shaking Water Bath															
2 Flask Growth															
Floor Incubator-Shaker															
Microscope															
3 Seed Fermentation															
Seed Bioreactor													78954	.5	●
4 Fermentation															
Production Bioreactor	500	25	.05	1	.035										
5 Whole Cell Harvest															
Harvest Heat Exchanger															
Harvest Vessel															
Agitator															
6 Cell Concentration															
Pump															
Filter Holder															
Manifolding															
Instrumentation															●
MF Flush Vessel															
MF Prime Vessel															
MF Filtrate Vessel															
Agitator															
MF Wash Vessel															
MF Regeneration Vessel															
MF Storage Vessel															

FIG. 64C

Equipment Maintenace Table - Microbial Fermentation

6418 / 6420

Equipment Items					Thermal Media						
			Labor		Materials					Labor	
	Unit Cost	$/Cycle	Hours	$/Cycle	Item No.	Qty	Cycle Life	Unit Cost	$/Cycle	Hours	$/Cycle
#1 Inoculum Prep											
-80 C Stock Freezer											
Shaking Water Bath											
#2 Flask Growth											
Floor Incubator-Shaker											
Microscope											
#3 Seed Fermentation											
Seed Bioreactor	1.5	.03	.5	.175							
#4 Fermentation											
Production Bioreactor					56258	5	500	.85	425	1	17.5
#5a Whole Cell Harvest											
Harvest Heat Exchanger											
Harvest Vessel											
Agitator											
#6 Cell Concentration											
Pump											
Filter Holder											
Manifolding											
Instrumentation											
MF Flush Vessel											
MF Prime Vessel											
MF Filtrate Vessel											
Agitator											
MF Wash Vessel											
MF Regeneration Vessel											
MF Storage Vessel											

FIG. 64D

Equipment Maintenace Table - Microbial Fermentation

Equipment Items	Filters							Gaskets							Bearings
	Materials					Labor		Materials					Labor		Materials
	Item No.	Qty	Cycle Life	Unit Cost	$/Cycle	Hours	$/Cycle	Item No.	Qty	Cycle Life	Unit Cost	$/Cycle	Hours	$/Cycle	Item No.
7. Cell Concentration #2															
MF Wash Vessel															
Pump															
Filter Holder															
Manifolding															
Instrumentation															
MF Flush Vessel															
MF Prime Vessel															
MF Filtrate Vessel															
MF Wash Vessel															
MF Regeneration Vessel															
MF Storage Vessel															
8. Cell Resuspension															
Resuspension Vessel															
Stir Plate															
9. Cell Disruption															
Cell Disruptor															
Lysate Vessel															
10. Resuspension #1 & 2															
Resuspension Vessel															
Stir Plate															
11. Concentration #1 & 2															
MF Wash Vessel															
Pump															
Filter Holder															

FIG. 64E

GC Equipment Maintenace Table - Microbial Fermentation

Equipment Items							Seals							Belts	
					Labor		Materials					Labor		Materials	
	Qty	Cycle Life	Unit Cost	$/Cycle	Hours	$/Cycle	Item No.	Qty	Cycle Life	Unit Cost	$/Cycle	Hours	$/Cycle	Item No.	Qty
7. Cell Concentration 2															
MF Wash Vessel															
Pump															
Filter Holder															
Manifolding															
Instrumentation															
MF Flush Vessel															
MF Prime Vessel															
MF Filtrate Vessel															
MF Wash Vessel															
MF Regeneration Vessel															
MF Storage Vessel															
8. Cell Resuspension															
Resuspension Vessel															
Stir Plate															
9. Cell Disruption															
Cell Disruptor															
Lysate Vessel															
10. B. Resuspension 1&2															
Resuspension Vessel															
Stir Plate															
11. B. Concentration 1&2															
MF Wash Vessel															
Pump															
Filter Holder															

FIG. 64F

Equipment Maintenace Table - Microbial Fermentation

Equipment Items				Labor		Shafts					Labor		Lubricant		
						Materials							Materials		
	Cycle Life	Unit Cost	$/Cycle	Hours	$/Cycle	Item No.	Qty	Cycle Life	Unit Cost	$/Cycle	Hours	$/Cycle	Item No.	Qty	Cycle Life
7A Cell Concentration 2															
MF Wash Vessel															
Pump															
Filter Holder															
Manifolding															
Instrumentation															
MF Flush Vessel															
MF Prime Vessel															
MF Filtrate Vessel															
MF Wash Vessel															
MF Regeneration Vessel															
MF Storage Vessel															
8A Cell Resuspension															
Resuspension Vessel															
Stir Plate															
9A Cell Disruption															
Cell Disruptor															
Lysate Vessel															
10A B Resuspension 1 & 2															
Resuspension Vessel															
Stir Plate															
11A B Concentration 1 & 2															
MF Wash Vessel															
Pump															
Filter Holder															

FIG. 64G

Equipment Maintenace Table - Microbial Fermentation

Equipment Items			Thermal Media								
			Labor		Materials					Labor	
	Unit Cost	$/Cycle	Hours	$/Cycle	Item No.	Qty	Cycle Life	Unit Cost	$/Cycle	Hours	$/Cycle
M7 Cell Concentration 2											
MF Wash Vessel											
Pump											
Filter Holder											
Manifolding											
Instrumentation											
MF Flush Vessel											
MF Prime Vessel											
MF Filtrate Vessel											
MF Wash Vessel											
MF Regeneration Vessel											
MF Storage Vessel											
M8 Cell Resuspension											
Resuspension Vessel											
Stir Plate											
M9 Cell Disruption											
Cell Disruptor											
Lysate Vessel											
M10 B Resuspension 1&2											
Resuspension Vessel											
Stir Plate											
M11 B Concentration 1&2											
MF Wash Vessel											
Pump											
Filter Holder											

FIG. 64H

Equipment Maintenace Table - Microbial Fermentation

Equipment Items	Filters							Gaskets							Bearings
	Materials					Labor		Materials					Labor		Materials
	Item No.	Qty	Cycle Life	Unit Cost	$/Cycle	Hours	$/Cycle	Item No.	Qty	Cycle Life	Unit Cost	$/Cycle	Hours	$/Cycle	Item No.
Manifolding															
Instrumentation															
MF Flush Vessel															
MF Prime Vessel															
MF Filtrate Vessel															
MF Dilute Vessel															
MF Wash Vessel															
MF Regeneration Vessel															
MF Storage Vessel															
114 Renaturation															
Renaturant Vessel															
Stir Plate															
115 Buffer Exchange															
Pump															
Filter Holder															
Manifolding															
Instrumentation															
UF Flush Vessel															
UF Prime Vessel															
UF Filtrate Vessel															
UF Wash Vessel															
UF Diluent Vessel															
UF Regeneration Vessel															
UF Storage Vessel															

FIG. 64I

Equipment Maintenace Table - Microbial Fermentation

Equipment Items							Seals							Belts	
					Labor		Materials					Labor		Materials	
	Qty	Cycle Life	Unit Cost	$/Cycle	Hours	$/Cycle	Item No.	Qty	Cycle Life	Unit Cost	$/Cycle	Hours	$/Cycle	Item No.	Qty
Manifolding															
Instrumentation															
MF Flush Vessel															
MF Prime Vessel															
MF Filtrate Vessel															
MF Dilute Vessel															
MF Wash Vessel															
MF Regeneration Vessel															
MF Storage Vessel															
14. Renaturation															
Renaturant Vessel															
Stir Plate															
15. Buffer Exchange															
Pump															
Filter Holder															
Manifolding															
Instrumentation															
UF Flush Vessel															
UF Prime Vessel															
UF Filtrate Vessel															
UF Wash Vessel															
UF Diluent Vessel															
UF Regeneration Vessel															
UF Storage Vessel															

FIG- 64J

Equipment Maintenace Table - Microbial Fermentation

Equipment Items				Labor		Shafts					Labor		Lubricant		
						Materials							Materials		
	Cycle Life	Unit Cost	$/Cycle	Hours	$/Cycle	Item No.	Qty	Cycle Life	Unit Cost	$/Cycle	Hours	$/Cycle	Item No.	Qty	Cycle Life
Manifolding															
Instrumentation															
MF Flush Vessel															
MF Prime Vessel															
MF Filtrate Vessel															
MF Dilute Vessel															
MF Wash Vessel															
MF Regeneration Vessel															
MF Storage Vessel															
14. Renaturation															
Renaturant Vessel															
Stir Plate															
15. Buffer Exchange															
Pump															
Filter Holder															
Manifolding															
Instrumentation															
UF Flush Vessel															
UF Prime Vessel															
UF Filtrate Vessel															
UF Wash Vessel															
UF Diluent Vessel															
UF Regeneration Vessel															
UF Storage Vessel															

FIG. 64K

Equipment Maintenace Table- Microbial Fermentation

Equipment Items			Labor		Thermal Media						
					Materials					Labor	
	Unit Cost	$/Cycle	Hours	$/Cycle	Item No.	Qty	Cycle Life	Unit Cost	$/Cycle	Hours	$/Cycle
Manifolding											
Instrumentation											
MF Flush Vessel											
MF Prime Vessel											
MF Filtrate Vessel											
MF Dilute Vessel											
MF Wash Vessel											
MF Regeneration Vessel											
MF Storage Vessel											
14 Renaturation											
Renaturant Vessel											
Stir Plate											
15 Buffer Exchange											
Pump											
Filter Holder											
Manifolding											
Instrumentation											
UF Flush Vessel											
UF Prime Vessel											
UF Filtrate Vessel											
UF Wash Vessel											
UF Diluent Vessel											
UF Regeneration Vessel											
UF Storage Vessel											

FIG. 64L

Equipment Maintenace Table - Microbial Fermentation

Equipment Items	Filters							Gaskets							Bearings
	Materials					Labor		Materials					Labor		Materials
	Item No.	Qty	Cycle Life	Unit Cost	$/Cycle	Hours	$/Cycle	Item No.	Qty	Cycle Life	Unit Cost	$/Cycle	Hours	$/Cycle	Item No.
UF Waste Vessel															
16 Chromatography 1															
Chromatography Column															
Pump															
Inst. & Control System															
Manifolding															
Equilibration Vessel															
Wash Vessel															
Eluent Vessel															
Regenerate Vessel															
Storage Vessel															
Waste Vessel (1)															
Product Vessel															
Waste Vessel (2)															
17 Chromatography 2															
Chromatography Column															
Pump															
Inst. & Control System															
Manifolding															
Equilibration Vessel															
Wash Vessel															
Eluent Vessel															
Regenerate Vessel															

FIG. 64M

Equipment Maintenace Table - Microbial Fermentation

Equipment Items					Labor		Seals					Labor		Belts	
							Materials							Materials	
	Qty	Cycle Life	Unit Cost	$/Cycle	Hours	$/Cycle	Item No.	Qty	Cycle Life	Unit Cost	$/Cycle	Hours	$/Cycle	Item No.	Qty
UF Waste Vessel															
16 Chromatography 1															
Chromatography Column															
Pump															
Inst. & Control System															
Manifolding															
Equilibration Vessel															
Wash Vessel															
Eluent Vessel															
Regenerate Vessel															
Storage Vessel															
Waste Vessel (1)															
Product Vessel															
Waste Vessel (2)															
17 Chromatography 2															
Chromatography Column															
Pump															
Inst. & Control System															
Manifolding															
Equilibration Vessel															
Wash Vessel															
Eluent Vessel															
Regenerate Vessel															

FIG. 64N

Equipment Maintenace Table - Microbial Fermentation

Equipment Items						Shafts							Lubricant		
				Labor		Materials					Labor		Materials		
	Cycle Life	Unit Cost	$/Cycle	Hours	$/Cycle	Item No.	Qty	Cycle Life	Unit Cost	$/Cycle	Hours	$/Cycle	Item No.	Qty	Cycle Life
UF Waste Vessel															
1.6 Chromatography1															
Chromatography Column															
Pump															
Inst. & Control System															
Manifolding															
Equilibration Vessel															
Wash Vessel															
Eluent Vessel															
Regenerate Vessel															
Storage Vessel															
Waste Vessel (1)															
Product Vessel															
Waste Vessel (2)															
1.7 Chromatography2															
Chromatography Column															
Pump															
Inst. & Control System															
Manifolding															
Equilibration Vessel															
Wash Vessel															
Eluent Vessel															
Regenerate Vessel															

FIG. 640

Equipment Maintenace Table - Microbial Fermentation

Equipment Items					Thermal Media						
			Labor		Materials					Labor	
	Unit Cost	$/Cycle	Hours	$/Cycle	Item No.	Qty	Cycle Life	Unit Cost	$/Cycle	Hours	$/Cycle
UF Waste Vessel											
16 Chromatography 1											
Chromatography Column											
Pump											
Inst. & Control System											
Manifolding											
Equilibration Vessel											
Wash Vessel											
Eluent Vessel											
Regenerate Vessel											
Storage Vessel											
Waste Vessel (1)											
Product Vessel											
Waste Vessel (2)											
17 Chromatography 2											
Chromatography Column											
Pump											
Inst. & Control System											
Manifolding											
Equilibration Vessel											
Wash Vessel											
Eluent Vessel											
Regenerate Vessel											

FIG. 64P

Equipment Maintenace Table - Microbial Fermentation

Equipment Items	Filters							Gaskets							Bearings
	Materials					Labor		Materials					Labor		Materials
	Item No.	Qty	Cycle Life	Unit Cost	$/Cycle	Hours	$/Cycle	Item No.	Qty	Cycle Life	Unit Cost	$/Cycle	Hours	$/Cycle	Item No.
Storage Vessel															
Waste Vessel (1)															
Product Vessel															
Waste Vessel (2)															
18 Buffer Exchange															
Pump															
Filter Holder															
Manifolding															
Instrumentation															
UF Flush Vessel															
UF Prime Vessel															
UF Filtrate Vessel															
UF Wash Vessel															
UF Diluent Vessel															
UF Regeneration Vessel															
UF Storage Vessel															
UF Waste Vessel															
19 Chromatography 3															
Chromatography Column															
Pump															
Inst. & Control System															
Manifolding															
Equilibration Vessel															

FIG. 64Q

Equipment Maintenace Table - Microbial Fermentation

Equipment Items							Seals							Belts	
					Labor		Materials					Labor		Materials	
	Qty	Cycle Life	Unit Cost	$/Cycle	Hours	$/Cycle	Item No.	Qty	Cycle Life	Unit Cost	$/Cycle	Hours	$/Cycle	Item No.	Qty
Storage Vessel															
Waste Vessel (1)															
Product Vessel															
Waste Vessel (2)															
18% Buffer Exchange															
Pump															
Filter Holder															
Manifolding															
Instrumentation															
UF Flush Vessel															
UF Prime Vessel															
UF Filtrate Vessel															
UF Wash Vessel															
UF Diluent Vessel															
UF Regeneration Vessel															
UF Storage Vessel															
UF Waste Vessel															
19% Chromatography 3															
Chromatography Column															
Pump															
Inst. & Control System															
Manifolding															
Equilibration Vessel															

FIG. 64R

Equipment Maintenace Table - Microbial Fermentation

Equipment Items				Labor		Shafts					Labor		Lubricant		
						Materials							Materials		
	Cycle Life	Unit Cost	$/Cycle	Hours	$/Cycle	Item No.	Qty	Cycle Life	Unit Cost	$/Cycle	Hours	$/Cycle	Item No.	Qty	Cycle Life
Storage Vessel															
Waste Vessel (1)															
Product Vessel															
Waste Vessel (2)															
18 Buffer Exchange															
Pump															
Filter Holder															
Manifolding															
Instrumentation															
UF Flush Vessel															
UF Prime Vessel															
UF Filtrate Vessel															
UF Wash Vessel															
UF Diluent Vessel															
UF Regeneration Vessel															
UF Storage Vessel															
UF Waste Vessel															
19 Chromatography 3															
Chromatography Column															
Pump															
Inst. & Control System															
Manifolding															
Equilibration Vessel															

FIG. 64S

Equipment Maintenace Table - Microbial Fermentation

Equipment Items					Thermal Media						
			Labor		Materials					Labor	
	Unit Cost	$/Cycle	Hours	$/Cycle	Item No.	Qty	Cycle Life	Unit Cost	$/Cycle	Hours	$/Cycle
Storage Vessel											
Waste Vessel (1)											
Product Vessel											
Waste Vessel (2)											
18 Buffer Exchange											
Pump											
Filter Holder											
Manifolding											
Instrumentation											
UF Flush Vessel											
UF Prime Vessel											
UF Filtrate Vessel											
UF Wash Vessel											
UF Diluent Vessel											
UF Regeneration Vessel											
UF Storage Vessel											
UF Waste Vessel											
19 Chromatography 3											
Chromatography Column											
Pump											
Inst. & Control System											
Manifolding											
Equilibration Vessel											

FIG. 64T

Equipment Maintenace Table - Microbial Fermentation

Equipment Items	Filters							Gaskets							Bearings
	Materials					Labor		Materials					Labor		Materials
	Item No.	Qty	Cycle Life	Unit Cost	$/Cycle	Hours	$/Cycle	Item No.	Qty	Cycle Life	Unit Cost	$/Cycle	Hours	$/Cycle	Item No.
Wash Vessel															
Eluent Vessel															
Regenerate Vessel															
Storage Vessel															
Waste Vessel (1)															
Product Vessel															
Waste Vessel (2)															
20 Buffer Exchange															
Pump															
Filter Holder															
Manifolding															
Instrumentation															
UF Flush Vessel															
UF Prime Vessel															
UF Filtrate Vessel															
UF Wash Vessel															
UF Diluent Vessel															
UF Regeneration Vessel															
UF Storage Vessel															
UF Waste Vessel															
21 Chromatography															
Chromatography Column															
Pump															

FIG. 64U

Equipment Maintenace Table - Microbial Fermentation

Equipment Items							Seals							Belts	
					Labor		Materials					Labor		Materials	
	Qty	Cycle Life	Unit Cost	$/Cycle	Hours	$/Cycle	Item No.	Qty	Cycle Life	Unit Cost	$/Cycle	Hours	$/Cycle	Item No.	Qty
Wash Vessel															
Eluent Vessel															
Regenerate Vessel															
Storage Vessel															
Waste Vessel (1)															
Product Vessel															
Waste Vessel (2)															
20. Buffer Exchange															
Pump															
Filter Holder															
Manifolding															
Instrumentation															
UF Flush Vessel															
UF Prime Vessel															
UF Filtrate Vessel															
UF Wash Vessel															
UF Diluent Vessel															
UF Regeneration Vessel															
UF Storage Vessel															
UF Waste Vessel															
21. Chromatography															
Chromatography Column															
Pump															

FIG. 64V

Equipment Maintenace Table - Microbial Fermentation

Equipment Items				Labor		Shafts					Labor		Lubricant		
						Materials							Materials		
	Cycle Life	Unit Cost	$/Cycle	Hours	$/Cycle	Item No.	Qty	Cycle Life	Unit Cost	$/Cycle	Hours	$/Cycle	Item No.	Qty	Cycle Life
Wash Vessel															
Eluent Vessel															
Regenerate Vessel															
Storage Vessel															
Waste Vessel (1)															
Product Vessel															
Waste Vessel (2)															
20 Buffer Exchange															
Pump															
Filter Holder															
Manifolding															
Instrumentation															
UF Flush Vessel															
UF Prime Vessel															
UF Filtrate Vessel															
UF Wash Vessel															
UF Diluent Vessel															
UF Regeneration Vessel															
UF Storage Vessel															
UF Waste Vessel															
21 Chromatography 4															
Chromatography Column															
Pump															

FIG. 64W

Equipment Maintenace Table - Microbial Fermentation

Equipment Items			Labor		Thermal Media						
					Materials					Labor	
	Unit Cost	$/Cycle	Hours	$/Cycle	Item No.	Qty	Cycle Life	Unit Cost	$/Cycle	Hours	$/Cycle
Wash Vessel											
Eluent Vessel											
Regenerate Vessel											
Storage Vessel											
Waste Vessel (1)											
Product Vessel											
Waste Vessel (2)											
20. Buffer Exchange											
Pump											
Filter Holder											
Manifolding											
Instrumentation											
UF Flush Vessel											
UF Prime Vessel											
UF Filtrate Vessel											
UF Wash Vessel											
UF Diluent Vessel											
UF Regeneration Vessel											
UF Storage Vessel											
UF Waste Vessel											
21. Chromatography 4											
Chromatography Column											
Pump											

FIG. 64X

Equipment Maintenace Table - Microbial Fermentation

Equipment Items	Filters							Gaskets							Bearings
	Materials					Labor		Materials					Labor		Materials
	Item No.	Qty	Cycle Life	Unit Cost	$/Cycle	Hours	$/Cycle	Item No.	Qty	Cycle Life	Unit Cost	$/Cycle	Hours	$/Cycle	Item No.
Inst. & Control System															
Manifolding															
Equilibration Vessel															
Wash Vessel															
Eluent Vessel															
Regenerate Vessel															
Storage Vessel															
Waste Vessel (1)															
Product Vessel															
Waste Vessel (2)															
22 Sterile Filtration															
MF Wash Vessel															
Pump															
Filter Holder															
Manifolding															
Instrumentation															
MF Flush Vessel															
MF Prime Vessel															
MF Filtrate Vessel															
MF Wash Vessel															

FIG. 64Y

Equipment Maintenace Table - Microbial Fermentation

Equipment Items							Seals							Belts	
					Labor		Materials					Labor		Materials	
	Qty	Cycle Life	Unit Cost	$/Cycle	Hours	$/Cycle	Item No.	Qty	Cycle Life	Unit Cost	$/Cycle	Hours	$/Cycle	Item No.	Qty
Inst. & Control System															
Manifolding															
Equilibration Vessel															
Wash Vessel															
Eluent Vessel															
Regenerate Vessel															
Storage Vessel															
Waste Vessel (1)															
Product Vessel															
Waste Vessel (2)															
22. Sterile Filtration															
MF Wash Vessel															
Pump															
Filter Holder															
Manifolding															
Instrumentation															
MF Flush Vessel															
MF Prime Vessel															
MF Filtrate Vessel															
MF Wash Vessel															

FIG. 642

Equipment Maintenace Table - Microbial Fermentation

Equipment Items						Shafts							Lubricant		
				Labor		Materials					Labor		Materials		
	Cycle Life	Unit Cost	$/Cycle	Hours	$/Cycle	Item No.	Qty	Cycle Life	Unit Cost	$/Cycle	Hours	$/Cycle	Item No.	Qty	Cycle Life
Inst. & Control System															
Manifolding															
Equilibration Vessel															
Wash Vessel															
Eluent Vessel															
Regenerate Vessel															
Storage Vessel															
Waste Vessel (1)															
Product Vessel															
Waste Vessel (2)															
22 Sterile Filtration															
MF Wash Vessel															
Pump															
Filter Holder															
Manifolding															
Instrumentation															
MF Flush Vessel															
MF Prime Vessel															
MF Filtrate Vessel															
MF Wash Vessel															

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FIG. 64 AA

Equipment Maintenace Table - Microbial Fermentation

Equipment Items					Thermal Media						
			Labor		Materials					Labor	
	Unit Cost	$/Cycle	Hours	$/Cycle	Item No.	Qty	Cycle Life	Unit Cost	$/Cycle	Hours	$/Cycle
Inst. & Control System											
Manifolding											
Equilibration Vessel											
Wash Vessel											
Eluent Vessel											
Regenerate Vessel											
Storage Vessel											
Waste Vessel (1)											
Product Vessel											
Waste Vessel (2)											
22. Sterile Filtration											
MF Wash Vessel											
Pump											
Filter Holder											
Manifolding											
Instrumentation											
MF Flush Vessel											
MF Prime Vessel											
MF Filtrate Vessel											
MF Wash Vessel											

FIG. 64AB

Master Process Parameters Table - Biopharmaceutical

	Unit Operation Type	Group 1 Parameter	Soln.		Group 2 Parameter	Soln.		Group 3 Parameter	Soln.	
T1	Inoculum Prep	Number of Flasks Media Volume/Flask		2 0.25 Liters	Temperature Agitation Duration		37 C 200 RPM 18 Hours	Final OD		12
T2	Flask Growth	Scale Up Ratio Media Volume/Flask		10 Fold 1.25 L	Temperature Agitation Duration		37 C 200 Hours 18 RPM	Final OD		12
T3	Fermentation Production	Scale Up Ratio Fermentor Working Volume Antifoam A Antifoam B Base Acid	S-101 S-102 S-103 S-104 S-105	10 Fold 500 Liters 1 Ml/L 1 Ml/L 5 Ml/L 5 Ml/L	Growth Temperature Agitation Sparge Rate Back Pressure Total Duration		37 Hours 1 HP/100L 1.5 VVM 5 PSIG 21 Hrs	Final OD Dry Cell Mass Product Concentration CIP		12 9.96 Gms TDCM/L 0.3 Gms Product/L Y
T4	Initial seeding	Number of Ampules Volume Per Ampule Sarting Cell Density Ampule Split Ratio Culture Vessel Type Feed Volume		2 2 Ml 300,000 Cells/Ml 1 Vessels/Ampule Roll. Bot. 100 Ml	Serum Content Feed Rate Days to Confluence		2.0% Fetal Bovine Serum 1 Feed per vessel per 2 Days 2 Days	Amplification Factor		100%
T5	Culture Vessel Split	Vessel Split Ratio New Vessel Type Feed Volume Serum Content		2 RB 100 Ml 2.0% Fetal Bovine Serum	Feed Rate Days to Confluence		1 Feed per vessel per 2 Days 2 Days	Amplification Factor		100%
T6	Spinner Flask Seeding	Flask Feed Volume Vessel/Flask Ratio uCarrier Density Number of PBS Washs Number of Media Washs No. of Media/Serum Washs		4 Liters 0.1 L Cells/L Flask 5 Gm/Liter 2 1 2 FBS	Serum Content Feed Rate Days to Confluence		2.0% Fetal Bovine Serum 1 Feed per vessel per 2 Days 2 Days	Amplification Factor		100%
T7	Biosynthesis Bioreactor Preparation (Stirred Tank Reactor)	Reactor Feed Volume Spinner/Reactor Ratio uCarrier Density Number of PBS Washs Number of Media Washs No. of Media/Serum Washs		500 Liters 8.3 5 Gm/Liter 2 1 2	Serum Content Feed Rate Days to Confluence Serum Free Media Washes		2.0% Fetal Bovine Serum 1 Feed per vessel per 2 Days 10 Days 2	Product Concentration Total Protein Concen.		2500% Mg Prod/L 0.125 Mg TP/Ml
T8	Biosynthesis Bioreactor Preparation (Hollow Fiber Reactor)	Reactor Feed Volume Number of PBS Washs Number of Media Washs No. of Media/Serum Washs Serum Content		100 Liters 2 2 2 2.0% Fetal Bovine Serum	Number of Reactors Feed Rate Days to Confluence		1 1 Feed per vessel per 1 Days 10 Days	Harvest Volume Product Concentration Total Protein Concen.		500% Liters 25 Mg Prod/L 0.125 Mg TP/Ml
T9	Biosynthesis Bioreactor Preparation (Fluidized Bed Reactor)	Reactor Feed Volume uCarrier Density Number of PBS Washs Number of Media Washs No. of Media/Serum Washs Serum Content		Liters Gms/L	Number of Reactors Feed Rate Days to Confluence		1 1 Feed per vessel per 1 Days 10 Days	Product Concentration Total Protein Concen.		2500% Mg Prod/L 0.125 Mg TP/Ml
T10	Initial seeding	Number of Ampules Volume Per Ampule Sarting Cell Density Ampule Split Ratio		2 2 Ml 300,000 Cells/Ml 1 Vessels/Ampule	Serum Content Feed Rate Days to Confluence		2.0% Fetal Bovine Serum 1 Feed per vessel per 2 Days 2 Days	Amplification Factor		100%

Master Process Parameters Table - Biopharmaceutical

	Unit Operation Type	Group 1 Parameter	Soln.		Group 2 Parameter	Soln.		Group 3 Parameter	Soln.	
		Culture Vessel Type		Roll. Bot.	PBS Washes		200 Ml			
		Feed Volume		100 Ml	Trypsin Wash		100 Ml			
T11	Culture Vessel Split	Vessel Split Ratio		2	Feed Rate		1 Feed per vessel per	Amplification Factor		100%
		New Vessel Type		RB			2 Days			
		Feed Volume		100 Ml	Days to Confluence		2 Days			
		Serum Content		2.0% Fetal Bovine Serum	PBS Washes		200 Ml			
					Trypsin Wash		100 Ml			
T12	Spinner Flask Split	Flask Feed Volume		4 Liters	Serum Content		2.0% Fetal Bovine Serum	Amplification Factor		100%
		Vessel/Flask Ratio		0.1 L Cells/L Flask	Feed Rate		1 Feed per vessel per			
		uCarrier Density		5 Gm/Liter			2 Days			
		Number of PBS Washs		2	Days to Confluence		2 Days			
		Number of Media Washs		1						
		No. of Media/Serum Washs		2						
T13	Biosynthesis	Reactor Feed Volume		500 Liters	Serum Content		2.0% Fetal Bovine Serum	Product Concentration		2500% Mg Prod/L
	Bioreactor Preparation	Spinner/Reactor Ratio		8.3	Feed Rate		1 Feed per vessel per	Total Protein Concen.		0.125 Mg TP/Ml
	(Stirred Tank Reactor)	uCarrier Density		5 Gm/Liter			2 Days			
		Number of PBS Washs		2	Days to Confluence		10 Days			
		Number of Media Washs		1	Serum Free Media Washes		2			
		No. of Media/Serum Washs		2						
T14	Biosynthesis	Reactor Feed Volume		Liters	Number of Reactors		1	Product Concentration		2500% Mg Prod/L
	Bioreactor Preparation	uCarrier Density		Gms/L	Feed Rate		1 Feed per vessel per	Total Protein Concen.		0.125 Mg TP/Ml
	(Fluidized Bed Reactor)	Number of PBS Washs					1 Days			
		Number of Media Washs			Days to Confluence		10 Days			
		No. of Media/Serum Washs								
		Serum Content								
T15	Initial Coupling	Flask Feed Volume		4 Liters	Serum Content		2.0% Fetal Bovine Serum	Amplification Factor		100%
		Vessel/Flask Ratio		0.1 L Cells/L Flask	Feed Rate		1 Feed per vessel per			
		uCarrier Density		5 Gm/Liter			2 Days			
		Number of PBS Washs		2	Days to Confluence		2 Days			
		Number of Media Washs		1						
		No. of Media/Serum Washs		2 FBS						
T16	Additional Coupling	Reactor Feed Volume		500 Liters	Serum Content		2.0% Fetal Bovine Serum	Product Concentration		2500% Mg Prod/L
		Spinner/Reactor Ratio		8.3	Feed Rate		1 Feed per vessel per	Total Protein Concen.		0.125 Mg TP/Ml
		uCarrier Density		5 Gm/Liter			2 Days			
		Number of PBS Washs		2	Days to Confluence		10 Days			
		Number of Media Washs		1	Serum Free Media Washes		2			
		No. of Media/Serum Washs		2						
T17	Peptide Cleavage	Reactor Feed Volume		100 Liters	Number of Reactors		1	Harvest Volume		500% Liters
		Number of PBS Washs		2	Feed Rate		1 Feed per vessel per	Product Concentration		25 Mg Prod/L
		Number of Media Washs		2			1 Days	Total Protein Concen.		0.125 Mg TP/Ml
		No. of Media/Serum Washs		2	Days to Confluence		10 Days			
		Serum Content		2.0% Fetal Bovine Serum						
T18	Tissue Thawing	Crude Prduct Yeild		25 Gm Crude Prod./Kg Tissue	Contaminant Protein Conc.		100 Gm/L	Temperature Regulation		Y
		Enviromental Temperature		25 C				CIP		Y
		Thaw Duration		16 Hours				SIP		Y
T19	Homogenization	Crude Prduct Yeild		25 Gm Crude Prod./Kg Tissue	Contaminant Protein Conc.		100 Gm/L	Temperature Regulation		Y
		Liquid/Solid Ratio		10 L Solution/Kg Tissue				CIP		Y
		Hommogenization Temp.		4 C				SIP		Y
		Hommogenizer Type		RS						
		Energy Input		200 HP/100L/Hr						
		Duration		4 Hours						
T20	Liquid Thawing							Amplification Factor		100%

Master Process Parameters Table - Biopharmaceutical

	Unit Operation Type	Group 1 Parameter	Soln.		Group 2 Parameter	Soln.		Group 3 Parameter	Soln.	
T21	Product Ppt by Solids	Reagent Concetration		1 M	Kgms of Reagent/Liters Produ Temperature Addition Time Additional Mix Time		0.25 Kg/L 4 C 0.5 Hours 2 Hours	Step Recovery of Product Step Recovery of T.P. Temperature Regulation CIP SIP		95% 95% Y Y Y
T22	Product Ppt by Liquids	Reagent Concetration		1 M	Liters Reagent/Liters Product Temperature Addition Time Additional Mix Time		0.25 L/L 4 C 0.5 Hours 2 Hours	Step Recovery of Product Step Recovery of T.P. Temperature Regulation CIP SIP		95% 95% Y Y Y
T23	Contaminant Ppt by Solids	Reagent Concetration		1 M	Kgms of Reagent/Liters Produ Temperature Addition Time Additional Mix Time		0.25 Kg/L 4 C 0.5 Hours 2 Hours	Step Recovery of Product Step Recovery of T.P. Temperature Regulation CIP SIP		95% 95% Y Y Y
T24	Contaminant Ppt by Liquids	Reagent Concetration		1 M	Liters Reagent/Liters Product Temperature Addition Time Additional Mix Time		0.25 L/L 4 C 0.5 Hours 2 Hours	Step Recovery of Product Step Recovery of T.P. Temperature Regulation CIP SIP		95% 95% Y Y Y
T25	Solids Harvest Tangential Flow MF	Porosity Average Flux Rate Total Throughput Filtration Time		0.2 Micron 11 L/SF/HR at 40 Psig at 4 C 400 Liters/SF 1 HR	Flush Prime Concetration Factor Wash Regenerate Store		2 L/SF 2 L/SF 10 Fold 0.5 L/SF 1 L/SF 2 L/SF	Step Recovery of Product Step Recovery of T.P. Temperature Regulation CIP SIP		95% 95% Y Y Y
T26	Continuous Centrifugation Solids Harvest	System Void Volume		5 Liters	RCF Time Volume Reduction Wash Volume		10,000 X G 60 Minutes 30 X Vol. Reduction 0.2 X System Void Volume	Step Recovery of Product Step Recovery of T.P. Temperature Regulation CIP SIP		95% 95% Y Y Y
T27	Continuous Centrifugation Supernatant Harvest	System Void Volume		6 Liters	RCF Time Volume Reduction Wash Volume		10,000 X G 30 Minutes 0.062 Vol. Reduction 1.5 X System Void Volume	Step Recovery of Product Step Recovery of T.P. Temperature Regulation CIP SIP		85% 0.3 Y Y Y
T28	Dilution	System Void Volume		6 Liters	RCF Time Volume Reduction Wash Volume		10000 X G 30 Minutes 16 X Vol. Reduction 1.5 X System Void Volume	Step Recovery of Product Step Recovery of T.P. Temperature Regulation CIP SIP		95% 0.95 Y Y Y
T29	Batch Centrifugation Solids Harvest	System Void Volume		6 Liters	RCF Time Volume Reduction Wash Volume		10000 X G 30 Minutes 16 X Vol. Reduction 1.5 X System Void Volume	Step Recovery of Product Step Recovery of T.P. Temperature Regulation CIP		95% 0.95 Y Y

		Group 1			Group 2			Group 3		
	Unit Operation Type	Parameter	Soln.		Parameter	Soln.		Parameter	Soln.	
								SIP		Y
T30	Batch Centrifugation Supernatant Harvest	System Void Volume		6 Liters	RCF Time Volume Reduction Wash Volume		10000 X G 30 Minutes 16 X Vol. Reduction 1.5 X System Void Volume	Step Recovery of Product Step Recovery of T.P. Temperature Regulation CIP SIP		95% 0.95 Y Y Y
T31	Cell Disruption High Press. Homogen.	Product Temperature Utility Temperature Void Volume		8 C 2 C 5 Liters	Number of Passes Pressure Flow Rate Temperature Increase		6 Times 12,000 PSI 5 LPM 1.8 Degrees C/1,000 PSI	Rinse Step Recovery of Product Step Recovery of T.P. Temperature Regulation CIP SIP		500% Void Volumes 95% 95% Y Y Y
T32	Cell Disruption Bead Mill	Number of Passes Bead Size Void Volume Flow Rate		2 0.5 LPM				Step Recovery of Product Step Recovery of T.P. Temperature Regulation CIP SIP		95% Y Y Y
T33	Cell Disruption Chemical Lysis	Reagent Temperature Exposure Time		0.5 M NaOH 4 C 2 Hours	Liters Reagent/Gm Product Titration		0.4 L/Gm 0 Ml/Liter	Step Recovery of Product Step Recovery of T.P. Temperature Regulation CIP SIP		95% Y Y Y
T34	Microfiltration Tangential Flow	Porosity Average Flux Rate Total Throughput Filtration Time		0.2 Micron 50 L/SF/HR at 40 Psig at 4 C 400 Liters/SF 2 HR	Flush Prime Wash Solids Regenerate Store		2.00 L/SF 2.00 L/SF 0.50 L/SF 0.30% Of Product Solution 1.00 L/SF 2.00 L/SF	Step Recovery of Product Step Recovery of T.P. Temperature Regulation CIP SIP		95% 95% Y Y Y
T35	Microfiltration Dead End	Porosity Average Flux Rate Total Throughput Filtration Time		0.2 Micron 50 L/SF/HR at 40 Psig at 4 C 400 Liters/SF 0.5 HR	Flush Prime Wash Solids Regenerate Store		0 L/SF 0 L/SF 0.5 L/SF 0.003 Of Product Solution 1 L/SF 2 L/SF	Step Recovery of Product Step Recovery of T.P. Temperature Regulation CIP SIP		95% 0.95 N N N
T36	Ultrafiltration Concentration/Dilution	Porosity Average Flux Rate Concentration Time		60 K NMWL 3 L/SF/HR at 40 Psig at 4 C 2 HR	Flush Prime Wash Dilute Concentrate Solids Regenerate		2.00 L/SF 2.00 L/SF 0.50 L/SF 10.0 Fold 0.30% Of Product Solution 1.00 L/SF	Store Step Recovery of Product Step Recovery of T.P. Temperature Regulation CIP SIP		2.00 L/SF 95% 95% Y Y Y
T37	Ultrafiltration Flow Dialysis	Porosity Average Flux Rate Dialysis Time		60 K NMWL 3 L/SF/HR at 40 Psig at 4 C 2 HR	Flush Prime Dialysis Buffer Wash Solids Regenerate		2 L/SF 2.00 L/SF 5.0 X Feed Stream Volume 0.50 L/SF 0.30% Of Product Solution 1.00 L/SF	Store Step Recovery of Product Step Recovery of T.P. Temperature Regulation CIP SIP		200% L/SF 95% 95% Y Y Y
T38	Prod. Ads. Chromatography HPLC	Column Capacity Column Oversize Factor Column Aspect Ratio Max. Linear Velocity		10 MG Prod./Ml Of Packing 1.5 Fold 0.37 H/D 100 Cm/Hr at 45 Psig and 4 C	Column Equilibration Column Wash Column Elute A Column Elute B Column Regenerate Column Store		5 Column Volumes 3 Column Volumes 3 Column Volumes 0 Column Volumes 1 Column Volumes 2 Column Volumes	Prod. Elution Volume Step Recovery of Product Step Recovery of T.P. Temperature Regulation CIP SIP		80% 95% 95% N Y Y
T39	Prod. Ads. Chromatography MPLC	Column Capacity Column Oversize Factor		10 MG Prod./Ml Of Packing 1.5 Fold	Column Equilibration Column Wash		5 Column Volumes 3 Column Volumes	Prod. Elution Volume Step Recovery of Product		80% 95%

	Unit Operation Type	Group 1 Parameter	Soln.		Group 2 Parameter	Soln.		Group 3 Parameter	Soln.	
		Column Aspect Ratio Max. Linear Velocity		0.37 H/D 100 Cm/Hr at 45 Psig and 4 C	Column Elute A Column Elute B Column Regenerate Column Store		3 Column Volumes 0 Column Volumes 1 Column Volumes 2 Column Volumes	Step Recovery of T.P. Temperature Regulation CIP SIP		95% N Y Y
T40	Prod. Ads. Chromatography LPLC	Column Capacity Column Oversize Factor Column Aspect Ratio Max. Linear Velocity		10 MG Prod./Ml Of Packing 1.5 Fold 0.37 H/D 100 Cm/Hr at 45 Psig and 4 C	Column Equilibration Column Wash Column Elute A Column Elute B Column Regenerate Column Store		5 Column Volumes 3 Column Volumes 3 Column Volumes 2 Column Volumes 1 Column Volumes 2 Column Volumes	Prod. Elution Volume Step Recovery of Product Step Recovery of T.P. Temperature Regulation CIP SIP		42% 95% 95% N Y Y
T41	Cont. Ads. Chromatography HPLC	Column Capacity Column Oversize Factor Column Aspect Ratio Max. Linear Velocity		30 MG Cont./Ml Of Packing 1.5 Fold 0.37 H/D 100 Cm/Hr at 45 Psig and 4 C	Column Equilibration Column Wash Column Elute A Column Elute B Column Regenerate Column Store		5 Column Volumes 3 Column Volumes 3 Column Volumes 2 Column Volumes 1 Column Volumes 2 Column Volumes	Prod. Elution Volume Step Recovery of Product Step Recovery of T.P. Temperature Regulation CIP SIP		42% 95% 95% N Y Y
T42	Cont. Ads. Chromatography MPLC	Column Capacity Column Oversize Factor Column Aspect Ratio Max. Linear Velocity		10 MG Cont./Ml Of Packing 1.5 Fold 0.37 H/D 100 Cm/Hr at 45 Psig and 400% C	Column Equilibration Column Wash Column Elute A Column Elute B Column Regenerate Column Store		5 Column Volumes 3 Column Volumes 3 Column Volumes 2 Column Volumes 1 Column Volumes 2 Column Volumes	Prod. Elution Volume Step Recovery of Product Step Recovery of T.P. Temperature Regulation CIP SIP		42% 95% 95% N Y Y
T43	Cont. Ads. Chromatography LPLC	Column Capacity Column Oversize Factor Column Aspect Ratio Max. Linear Velocity		10 MG Cont./Ml Of Packing 1.5 Fold 0.37 H/D 100 Cm/Hr at 45 Psig and 4 C	Column Equilibration Column Wash Column Elute A Column Elute B Column Regenerate Column Store		5 Column Volumes 3 Column Volumes 3 Column Volumes 2 Column Volumes 1 Column Volumes 2 Column Volumes	Prod. Elution Volume Step Recovery of Product Step Recovery of T.P. Temperature Regulation CIP SIP		42% Columns Volumes 95% 95% N Y Y
T44	Size Excl. Chromatography HPLC	Load Capacity Length Max. Linear Velocity Void Volume		5% of Total Column Volume 100 Cm 100 Cm/Hr at 45 Psig and 4 C 25% Column Volume	Column Equilibration Column Wash Column Regenerate Column Store		4 Column Volumes 1 Column Volumes 1 Column Volumes 2 Column Volumes	Prod. Elution Volume Step Recovery of Product Step Recovery of T.P. Temperature Regulation CIP SIP		42% Columns Volumes 95% 95% N Y Y
T45	Size Excl. Chromatography MPLC	Load Capacity Length Max. Linear Velocity Void Volume		5% of Total Column Volume 100 Cm 100 Cm/Hr at 45 Psig and 4 C 25% Column Volume	Column Equilibration Column Wash Column Regenerate Column Store		4 Column Volumes 1 Column Volumes 1 Column Volumes 2 Column Volumes	Prod. Elution Volume Step Recovery of Product Step Recovery of T.P. Temperature Regulation CIP SIP		42% Columns Volumes 95% 95% N Y Y
T46	Size Excl. Chromatography LPLC	Load Capacity Length Max. Linear Velocity Void Volume		5% of Total Column Volume 100 Cm 100 Cm/Hr at 45 Psig and 4 C 25% Column Volume	Column Equilibration Column Wash Column Regenerate Column Store		4 Column Volumes 1 Column Volumes 1 Column Volumes 2 Column Volumes	Prod. Elution Volume Step Recovery of Product Step Recovery of T.P. Temperature Regulation CIP SIP		42% Columns Volumes 95% 95% N Y Y
T47	Dilution	Dilution Factor		3 Liters/Liter	Dilution Time Additional Mix Time		0.5 Hours 1 Hours	Step Recovery of Product Step Recovery of T.P. Temperature Regulation CIP SIP		95% 95% Y Y Y
T48	Resolubilization	Reagent/Product Ratio Dissolution Time Additional Mix Time		0 L/Kg Product 0.50 Hours 0.50 Hours	Reagent 1 Concentration		Water Dist.	Step Recovery of Product Step Recovery of T.P. Temperature Regulation CIP SIP		95% 95% Y Y Y

Master Process Parameters Table - Biopharmaceutical

	Unit Operation Type	Group 1			Group 2			Group 3		
		Parameter	Soln.		Parameter	Soln.		Parameter	Soln.	
T49	Enzymatic Modification	Enzyme to Product Ratio		0.084 Liters of Enzyme Stock Per Liter of Start. Proc. Vol.	Titration Solution -1		0.007 L/L Process	Step Recovery of Product		95%
					Titration Solution -2		0.02 L/L Process	Step Recovery of T.P.		95%
		Enzyme Concentration		2 Mg/Ml	Neutralization		0.57 L/L Process			
		Reaction Temp.		37 Degrees C				Temperature Regulation		Y
		Reaction Duration		30 Minutes				CIP		Y
				100%				SIP		Y
T50	Lyophilization	Product Capacity/Load		8 Units	Lyophilization Time		18 Hours	Step Recovery of Product		95%
		Product Unit Size		100 Grams/Unit	Product Weight Reduction		0.95	Step Recovery of T.P.		95%
										Y
								CIP		Y
								SIP		Y
T51	Heat Exchange	Process Initial Temp.		98.6 Degrees C	Exposure Time		1 Hours	Step Recovery of Product		100%
		Process Final Temp		39.2 Degrees C				Step Recovery of T.P.		100%
		Utility Initial Temp		34 Degrees C						
		Utility Final Temp.		5 Degrees C				Temperature Regulation		Y
		Process Specific Heat		38.6 K BTU/Hr				CIP		Y
		Design Type (P,T,C)		P				SIP		Y
T52	Storage							Step Recovery of Product		95%
								Step Recovery of T.P.		95%
								Temperature Regulation		Y
								CIP		Y
								SIP		Y
T53	Fermentation	Scale Up Ratio		10 Fold	Growth Temperature		37 Hours	Final OD		12
	Seed	Fermentor Working Volume		50 Liters	Agitation		1 HP/100L	CIP		
		Antifoam A		1 Ml/L	Sparge Rate		1.5 VVM			
		Antifoam B		1 Ml/L	Back Pressure		5 PSIG			Y
		Base		5 Ml/L	Total Duration		21 Hrs			
		Acid		5 Ml/L						
54	Initial Seeding	Flask Feed Volume		12 Liters	Serum Content		2% FBS	Amplification Factor		1
		Spinner Split Ratio		4	Feed Rate		1 Feed per vessel per			
		uCarrier Density		5 Gm/Liter			2 Days			
		Number of PBS Washs		2	Days to Confluence		2 Days			
		Number of Media Washs		1						
		No. of Media/Serum Washs		2 FBS						
55	Culture Vessel Split	Flask Feed Volume		12 Liters	Serum Content		2% FBS	Amplification Factor		1
		Spinner Split Ratio		4	Feed Rate		1 Feed per vessel per			
		uCarrier Density		5 Gm/Liter			2 Days			
		Number of PBS Washs		2	Days to Confluence		2 Days			
		Number of Media Washs		1						
		No. of Media/Serum Washs		2 FBS						
56	Culture Flask Split									
57	Stirred Tank Reactor							Step Recovery of Product		0.95
								Step Recovery of T.P.		95%
										Y
								CIP		Y
								SIP		Y
58	Fluidized Bed Reactor	Process Initial Temp.		37 Degrees C	Exposure Time		50% Hours	Step Recovery of Product		0.95
		Process Final Temp		4 Degrees C				Step Recovery of T.P.		100%
		Utility Initial Temp		2 Degrees C						

	Unit Operation Type	Group 1			Group 2			Group 3		
		Parameter	Soln.		Parameter	Soln.		Parameter	Soln.	
		Utility Final Temp.		5 Degrees C				Temperature Regulation		Y
		Process Specific Heat		12 K BTU/Hr				CIP		Y
		Design Type (P,T,C)		P				SIP		Y
59	Liquid/Liquid Extraction	Liquid/Liquid Ratio		1 L Extraction/L Product	Phase Separation Time		1600% Hours	Step Recovery of Product		0.9
		Extraction Temperature		4 C	Product Phase (Top/Bottom)		Top	Step Recovery of T.P.		50%
		Addition Duration		0.5 Hours	Harvest Time		0.5 Hours			
		Additional Mix Duration		4 Hours				Temperature Regulation		Y
		Mix Energy		0.3 HP/100 L				CIP		Y
								SIP		Y
60	Solid/Liquid Extraction	Liquid/Liquid Ratio		1 L Extraction/L Product	Phase Separation Time		1600% Hours	Step Recovery of Product		0.9
		Extraction Temperature		4 C	Product Phase (Top/Bottom)		Top	Step Recovery of T.P.		50%
		Duration		4 Hours	Harvest Time		0.5 Hours			
		Mix Energy		0.3 HP/100 L				Temperature Regulation		Y
								CIP		Y
								SIP		Y